DOE G 460.1-1A

xx-xx-07

IMPLEMENTATION GUIDE
for Use with
DOE O 460.1C,

PACKAGING AND TRANSPORTATION SAFETY

ASSISTANT SECRETARY FOR
ENVIRONMENTAL MANAGEMENT

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Foreword

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DOE Guides are part of the DOE Directives System and are issued to provide supplemental information regarding the Department's expectations of its requirements as contained in rules, Orders, notices, and regulatory standards. Guides may also provide acceptable methods for implementing these requirements. Guides are not substitutes for requirements, nor do they replace technical standards used to describe established practices and procedures for implementing requirements.

DOE and its contractors are responsible for basic and applied research; product development; and designing, constructing, operating, modifying, and decommissioning DOE facilities and sites to effectively accomplish DOE's missions and objectives. This work must be accomplished while minimizing potential hazards to the public, site or facility workers, and the environment. DOE O 460.1C, *Packaging and Transportation Safety*, xx-xx-07, prescribes a comprehensive safety program for the DOE and DOE-contractor packaging and transportation operations.

This *Guide* provides information concerning the use of current principles and practices, including regulatory guidance from the U.S. Department of Transportation and the U.S. Nuclear Regulatory Commission, where available, to establish and implement effective packaging and transportation safety programs. The intent of this *Guide* is to aid in the development of implementation plans to effectively carry out the requirements and responsibilities of the Order.

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Contents

ATTACHMENTS

FIGURES

TABLE

PACKAGING AND TRANSPORTATION SAFETY

I. INTRODUCTION

This Guide supplements the Department of Energy (DOE) Order, DOE O 460.1C, *Packaging and Transportation Safety*, xx-xx-07, by providing clarifying material for the implementation of packaging and transportation safety of hazardous materials. DOE O 460.1C replaces DOE O 460.1B, *Packaging and Transportation Safety*, April 4, 2003.

II. APPLICABILITY

This Guide should be considered when establishing the onsite and offsite packaging and transportation safety programs for a facility. Opportunities exist for demonstration of compliance to the Order by actions other than those set forth in this Guide. However, if a provision in this Guide is included explicitly in a contract, an enforceable obligation is thereby created in the contract.

1. Department of Energy Elements

Except for the exclusions in paragraph 3, below, the Order applies to all DOE Elements.

2. Contractors

Except for the exclusions cited below in paragraph 3 the Contractor Requirements Document (CRD), attached to the Order, establishes requirements to be applied to contractors awarded contracts for managing and operating DOE facilities. Contractor compliance with the CRD will be required to the extent set forth in a contract. Contractors shall be directed to continue to comply with the requirements of Orders canceled by the current Order until their contracts are modified to delete the reference to the requirements of the canceled Orders.

3. Exclusions

Activities regulated through a license by the Nuclear Regulatory Commission (NRC) or a state under an agreement with the NRC, including activities certified by the NRC under Section 1701 of the

Atomic Energy Act. Requirements of the Order that overlap or duplicate the requirements of the NRC related to radiation protection, nuclear safety (including quality assurance), and safeguards and security of nuclear material, do not apply to the Office of Civilian Radioactive Waste Management facilities.

Excluded from the requirements of the Order are: classified shipments; shipments of nuclear explosives, components, and special assemblies (see DOE O 461.1A, *Packaging and Transfer or Transportation of Materials of National Security Interest*, April 26, 2004.); and facilities and activities of the Naval Nuclear Propulsion Program (see Executive Order 12344).

III. GENERAL INFORMATION

The basis of the offsite safety requirements for this Order is given in Paragraph 4.a.(1) stating each person who offers for transportation or transports a package of hazardous materials shall comply with the DOT's Hazardous Materials Regulations (49 CFR 171–180) and applicable tribal, State, and local regulations. Relief from any of these requirements is obtained only by a DOT Special Permit request [Paragraph 4.f.(1)], submitted through EM or by DOE Exemption request [Paragraph 4.f.(2)].

In 1991, in response to an inquiry from Ms. Susan Denny, DOE Transportation Management Division, about the definition of "public highway," DOT replied as shown in Attachment 2. This response restated that DOE and DOE contractors qualify as a "person" within the meaning of the Hazardous Materials Transportation Uniform Safety Act of 1990. The response also restated that DOE contractors must comply with the Hazardous Materials Regulations even when transportation is in a government vehicle if the shipment was deemed "in commerce." Another important provision of this DOT response was to clarify that the meaning of "in commerce" is transport over roads to which the public had unrestricted access. The requirements necessary to prohibit "public access" and meet the definition of "not in commerce" (or the more commonly used term "onsite") were stated in this letter. This important interpretation by DOT is frequently referred to as the *Susan Denny Letter* and is included for its continuing importance to proper DOE operations.

In 1993, DOT declared in a written opinion to DOE that State agency (e.g., University of Georgia) employees of DOE contractors are not subject to all the provisions of the Hazardous Materials Transportation Act. As a result, DOE has included the employees of these exempt entities in this Order as if they were DOE employees, and so states in Paragraph 3.b.(2)(b). The DOT letter on this

subject is included in Attachment 3. The entities determined to exist in this category are:

Lawrence Livermore National Laboratory (University of California)
Lawrence Berkeley Laboratory (University of California)
Ames Laboratory (Iowa State University)
Savannah River Ecology Laboratory (University of Georgia)

The following section contains guidelines for the items in DOE O 460.1C unique to DOE requirements; that is, the guidelines do not include counsel for compliance with the DOT or NRC regulations per se.

IV. GUIDELINES

Some of the responsibilities defined in DOE O 460.1C for EM, other secretarial offices, and the heads of operations or field offices are further clarified in the following sections. Table IV.1 shows a matrix that describes where the responsibilities from DOE O 460.1C may be found in the various subsections of this Guide. Where a responsibility was deemed to be self-explanatory in the Order, no further guidance or interpretation is presented herein. The contractor's responsibilities are found in the Contractor Requirements Document, Attachment 1 to DOE O 460.1C. Guidance for contractor's responsibilities is provided as appropriate in this Guide.

1. Offsite Packaging And Transportation Safety

Hazardous materials shipments prepared or performed by DOE contractor's offsite at a DOE facility or, as defined by DOT, "in commerce," are subject to the Hazardous Materials Regulations of DOT. Contractors who operate DOE vehicles in interstate commerce or transport hazardous materials intrastate are subject to the Federal Motor Carrier Safety Regulations of the Federal Highway Administration. DOE O 460.1C requires DOE employees and contractors who are employees of State agencies to comply with the Hazardous Materials Regulations and the Federal Motor Carrier Safety Regulations as if they were regulated by DOT. Interpretation has been provided by DOT (Attachments 2 and 3) as to what constitutes "in commerce," how facility shipments may be taken out of commerce and the applicability of the Hazardous Materials Transportation Act to State or local entities and their employees. This guidance document focuses on the requirements imposed by DOE O 460.1C.

There are some responsibilities related to offsite transportation safety imposed by the Order on the DOE Program and Operations Offices. The Contractor Requirements Document, when made a part of the contracts, defines the responsibilities of the contractor for compliance with DOT for offsite shipments or with DOE, if a State agency is the contractor.

Table IV.1 DOE O 460.1C Responsibility Matrix with Guidance Document

Responsible Party	DOE O 460.1C	GUIDE
Office of Environmental Management	5.a.(1)	4.3
	5.a.(2)	??
	5.a.(3)	??
	5.a.(4)	4.2
	5.a.(5)	4.1, 4.2
	5.a.(6)	SE*
	5.a.(7)	SE*
	5.a.(8)	3.0
	5.a.(9)	2.0
	5.a.(10)	4.4
	5.a.(11)	SE*
	5.a.(12)	SE*
	5.a.(13)	SE*
	5.a.(14)	SE*
	5.a.(15)	??
	5.a.(16)	??
	5.a.(17)	??
Heads of Operations Offices or Field Offices/Site Office Manager	5.b.(1)	SE*
	5.b.(2)	5.0
	5.b.(3)	2.0, 3.0, 4.4
	5.b.(4)	4.3
	5.b.(5)	SE*
	5.b.(6)	SE*
	5.b.(7)	SE*
	5.b.(8)	??
	5.b.(9)	??

*SE = Self explanatory in the Order. No further guidance or interpretation provided in the *Guide.*

2. Guidance For Department of Energy Exemptions

DOE may grant temporary or permanent exemptions to its directives provided such requests are not prohibited by law and do not present an undue risk to public health and safety, the environment, or facility workers. This Guide describes an acceptable procedure and suggested outline to be used to request and grant exemptions to DOE O 460.1C.

2.1 Content and Format for Submittal

The requesting organization submits the request for an exemption with supporting justification to the Field Office or Operations Office Manager. The DOE Manual, DOE M 251.1-1B, *Departmental Directives Program Manual*, August 16, 2006, provides the following as guidance for the contents of the application.

a. Requests for exemptions must include the following information:

- Site or facility for which an exemption is being requested.
- Reference to the requirements for which exemption is sought.
- Identification and justification of the acceptance of any additional risks that will be incurred if the exemption is granted.
- Benefits to be realized by providing the exemption.
- Whether the exemption being requested is temporary or permanent and for temporary exemptions, indication of when compliance will be achieved.
- Identification of other pertinent data or information used as a basis for obtaining an exemption.

b. Requests for exemptions to environment, safety, and health requirements must also address the following:

- A description of any special circumstances that warrant the granting of an exemption, including whether—
  - application of the requirement in the particular circumstances would conflict with another requirement;
  - application of the requirement in the particular circumstances would not achieve, or is not necessary to achieve its underlying purpose;
  - application of the requirement in the particular circumstances would not be justified by any safety and health benefit;

- the exemption would result in a health and safety benefit that compensates for any detriment that would result from granting the exemption; or

- other material circumstances that exist were not considered when the requirement was adopted for which it is in the public interest to grant an exemption.

- Steps to be taken to provide adequate protection of health, safety, and the environment, and a statement that adequate protection will be provided.
- A description of any alternative or mitigating actions that have been, or will be, taken to ensure adequate safety and health and protection of the public, the workers, and the environment for the period the exemption will be effective.

In addition to the above material in DOE M 251.1-1B, information concerning the quantity and characterization of the materials to be packaged and transferred should be supplied. The Hazardous Materials Regulations provides additional guidance for application for a special permit for exemption from a DOT regulation (49 CFR 107.105).

2.2 Review Process Guidance

2.2.1 Operations Office Responsibility Guidance.

The first responsibility falls on the Operations Office to review the application and provide a recommendation and support of the evaluation of the exemption request to EM. The Operations Office also has the responsibility of transmitting the approval/disapproval letter to the requesting organization following the determination by EM. Procedures should be developed and implemented to meet the above responsibilities.

2.2.2 Evaluation Guidance for EM.

The request for exemption may be approved, rejected, or returned with directions on how to change the request to make it acceptable. Through consultation with the requesting organization, the request may be modified and EM may approve a modified exemption.

2.2.3 Requesting Organization.

The requesting organization should (a) provide sufficient detail in the request to support the application, (b) provide additional support and information to EM as requested during the evaluation process, and (c) follow the exemption decision including any terms and conditions to the exemption.

3. Guidance for Department of Transportation Special Permits

Special Permits issued by DOT to the Hazardous Materials Regulations are required if the shipper is unable to comply with any part of the applicable Hazardous Materials Regulations. Such administrative relief to the requirements will only be granted on the basis of equivalent levels of safety or levels of safety consistent with the public interest and the policy of the Federal law. DOE O 460.1C requires that the DOE shipper process applications for DOT special permits first through the cognizant Operations Office, then to EM for review. Since many contractors may have a need to use the special permit, this method provides issuance of the special permit to DOE as the holder. Each of the contractors with a need to utilize the special permit must submit an application for party status to DOT. Notice of such application should be made to the cognizant Operations Office.

All contractors should follow the following steps for obtaining a DOT special permit or existing special permit renewal:

a. Determine there is no means other than a special permit to accomplish a necessary transport. Considering the review time required by DOT and EM, the contractor should plan his submission accordingly.

b. Prepare an application for administrative relief following the instructions provided at 49 CFR 107.105 for a new application, 49 CFR 107.107 for party status, or 49 CFR 107.109 for a renewal application.

c. Submit application to the cognizant Operations Office for transmittal to EM. Applications for modifications to existing special permits should be transmitted to EM one hundred fifty (150) days before intended use or expiration. Renewal applications should be transmitted to EM ninety (90) days before expiration or intended use.

d. Once authorized, a copy of the DOT special permit must accompany the applicable shipments and users comply with specific restrictions in each special permit.

EM should provide as thorough a review as warranted on a graded scale. If the application is not for a one-time use or will likely be used by other contractors, EM should technically evaluate the application, assuring that all requirements of 49 CFR for such applications are met, and the application is necessary or continues to be necessary for the accomplishment of the DOE mission.

EM maintains a current register of DOT special permits and party-to-special permits issued to DOE. This information is available from the RAMPAC website.

4. Special Packaging for Radioactive Materials

The Hazardous Materials Regulations address packagings suitable for shipping radioactive materials in 49 CFR 173 and 49 CFR 178. Packaging for Low Specific Activity (LSA) or Surface Contaminated Object (SCO) may be Industrial Packaging Types 1, 2, and 3 (IP-1, IP-2, IP-3). Packaging for Type A quantities of radioactive materials may be either DOT-specification packagings (some are usable until October 1, 2008), Type A packagings designed and tested commercially, Type B certified (DOE or NRC) packagings, or DOE designed and tested Type A packagings. DOT permits DOE to certify Type B and fissile packagings for its own use (49 CFR 173.7). In addition, DOT regulations invoke the NRC regulations, 10 CFR 71, for certification of Type B and fissile packagings. Industrial Packagings, DOE-designed and -tested Type A packagings and DOE-certified Type B packagings are the subject of the following guidance information.

4.1 Industrial Packages

Industrial Packagings (IPs) are designed for relatively low-hazard shipments (i.e., LSA, SCO). DOE O 460.1C requires the establishment of a test and evaluation program for IP designs to be used for transportation of radioactive materials. In accordance with the Order, Industrial Packagings developed by DOE facilities will undergo testing by a DOE-approved test facility and then be approved by EM before use by DOE or its contractors.

Required test conditions simulate normal conditions of transport (including rough handling), not accident scenarios. Table IV.2 summarizes the IP test requirements.

Table IV.2 Industrial Package Type and Testing Requirements

Package Type	Required Tests
IP-1	none
IP-2	49 CFR 173.465(c), Free Drop (d), Stacking
IP-3	49 CFR 173.465(c), Free Drop (d), Stacking

49 CFR 173, *Shippers—General Requirements for Shipments and Packagings*

In accordance with 49 CFR 173.411(c), the responsibilities for ensuring a package meets all regulatory requirements at the time of shipment, including testing, are placed on the shipper (offeror). The tester of an IP must document for the shipper the testing conducted, how it was carried out and the effects of testing on the surrogate load and subsequent safety of the packaging. Consistent with a graded approach to safety, the IP test report need not be approved by DOE prior to shipment. A DOE-approved test facility approved for testing of Type A packagings described in Section 4.2 is recommended for IP testing.

4.2 Department of Energy Approved Type A Packages

This section presents guidelines for: (1) establishing a packaging testing facility, including the criteria for package testing the facility should be capable of performing and quality assurance criteria that it should meet; (2) applying to have a DOE-designed DOT Specification 7A Type A packaging approved.

4.2.1 Responsibilities.

In accordance with DOE O 460.1C, EM is responsible for approving the contractor testing facilities and for documenting qualified DOT Specification 7A Type A packagings designed by DOE contractors and tested at DOE facilities. By extension of the latter responsibility, EM approves packagings it determines have been qualified to meet the test criteria of Attachment 4. Documentation of a qualified packaging entails providing the test report and approved documents to EM-60. If the contractor elects to use a DOE-approved Type A package, it is the user and shipper's responsibility to assure the packaging is qualified, compatible with the contents to be shipped and correctly used.

4.2.2 Contractor Testing Facilities Approval.

This section describes the EM test and evaluation program for DOT Specification 7A Type A packaging designs. The responsibilities for operating an EM approved test facility are given, and the relationships between the applicant (who desires to have a package design tested and approved), the test facility, and EM are described. These guidelines are for a facility designing packagings and wishes to be designated as a DOE-approved test facility.

4.2.2.1 DOE Test Program for DOT Specification 7A Type A Packaging Designs.

DOE O 460.1C requires the establishment of a test and evaluation program for DOT Specification 7A Type A radioactive material package designs. The program was established to ensure consistently high-quality testing and supporting documentation. In accordance with DOE O 460.1C, Type A packagings developed by DOE facilities will undergo testing by a DOE-approved test facility and then be approved by EM before use by DOE or its contractors. Figure IV.1 illustrates the procedural steps in preparing for and performing the tests and developing supporting documentation.

The regulations of 49 CFR 173.462, *Preparation of Specimens for Testing*, should be followed prior to testing each specimen to identify and record faults or damage. The packaging test facility must ensure the hardware tested complies with the design specifications and the simulated radioactive contents impose a maximum stress on the feature being tested. After each of the applicable tests, specified in Attachment 4, the packaging and shielding should be tested as required by 49 CFR 173.465. It is the responsibility of the packaging test facility to ensure the adequacy of the techniques used to analyze the package design.

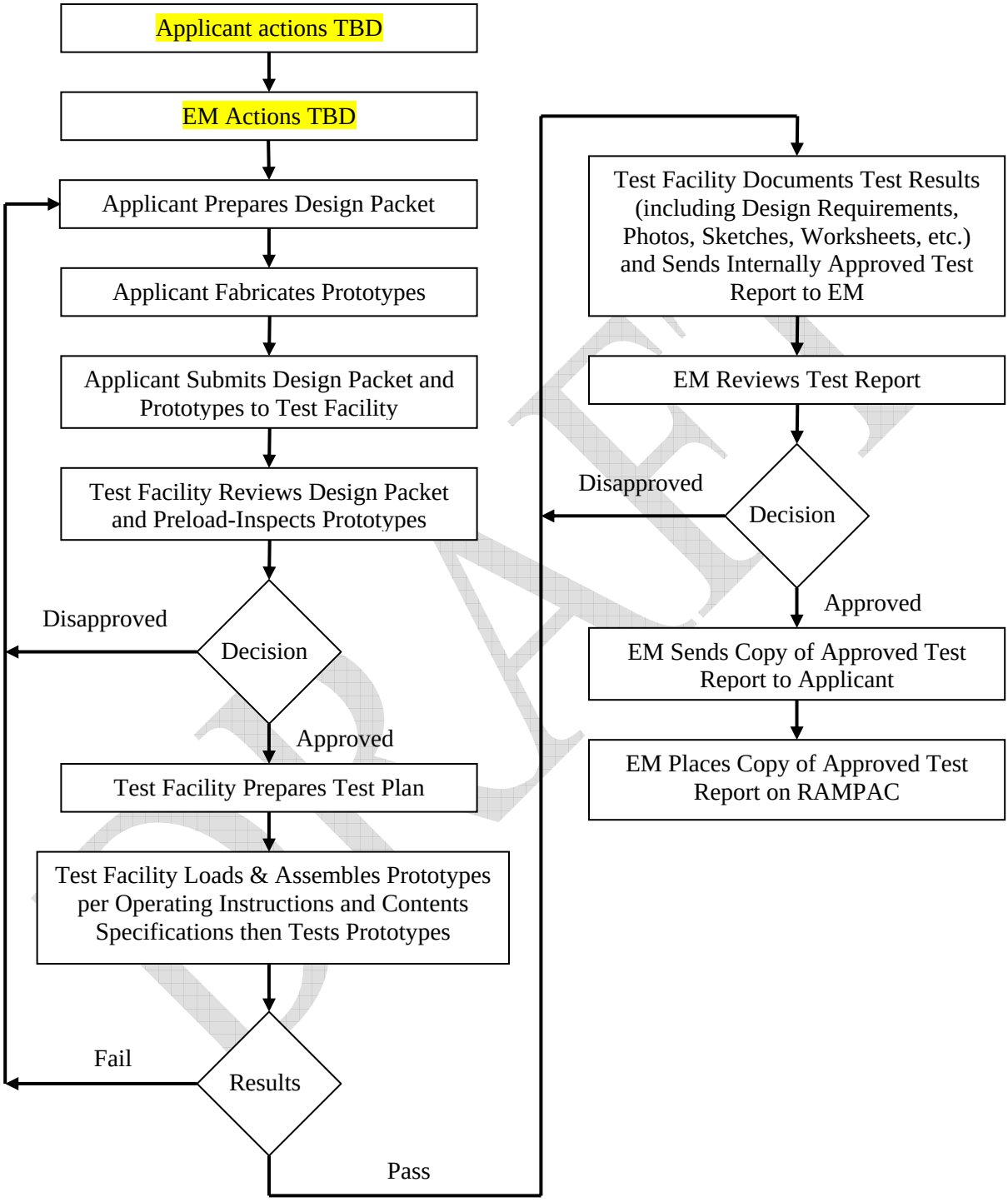

Figure IV.1 Procedural Steps for Testing and Approving a Type A Radioactive Material Packaging.

Following testing, the test facility develops complete documentation of the packaging evaluation and submits it to EM along with a copy to the applicant for comment. When the documentation of the packaging evaluation is approved by EM, the packaging is approved for use. When a packaging is approved, EM provides the applicant with a copy of the approved test report for the packaging. For designs which do not pass the Type A tests, documentation of the reason for failure is provided to the applicant by EM.

4.2.2.2 Procedure for Establishing a Test Facility.

Figure IV.2 illustrates the procedural steps for establishing a DOE-approved test facility. First, the candidate test facility should develop a detailed set of procedures documenting every aspect of its proposed Type A packaging evaluation activities. Guidance is provided in Section 4.2.1.3.1 regarding recommended content of test procedures. Procedures should also cover interactions between the test facility and the applicant, interactions between the test facility and EM, and preparation and distribution of documentation

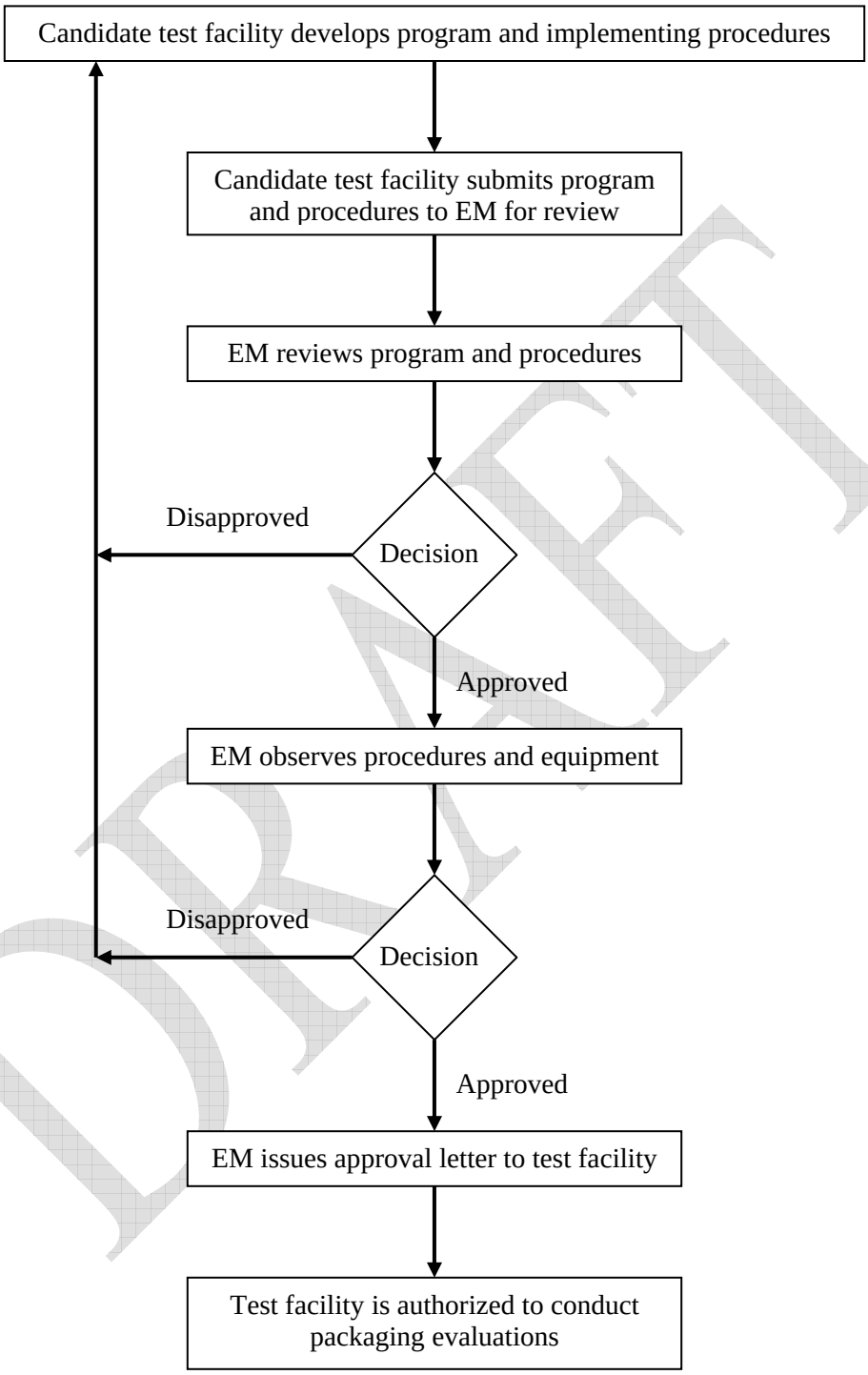

Figure IV.2 Procedural Steps for Establishing a Type A Test Program at a Test Facility.

EM may choose to review any aspect of a test facility's operation, and may require additional changes to the procedures or withdraw its approval of the test facility. EM approval of a tested packaging is still required before a packaging may be used for transport.

4.2.2.3 Established Requirements for Type A Packaging.

The test facilities are responsible for ensuring regulatory requirements, DOE Orders, and management directives pertaining to the design and performance of Type A packagings are met. The regulatory requirements are contained in 49 CFR 173.24, 173.24a, 173.24b, 173.410, 173.412, 173.461–462, 173.465, 173.466, and 178.350. Some of these requirements pertain to all hazardous materials packagings. Others pertain to Type A packagings only. Only those requirements related to packaging design and performance are verified by this program. The test facilities are responsible for ensuring all types of requirements are met. Table IV.3 summarizes the Type A test requirements.

Table IV.3 Material Classification, Package Type and Testing Requirements

Material Classification	Package Type	Required Tests
Type A Quantity (Solids)	Specification 7A Type A (for Solids)	49 CFR 173.465 (a), application (b), Water Spray (c), Free Drop (d), Stacking (e), Penetration
Type A Quantity (Liquids and Gases)	Specification 7A Type A (for Liquids and Gases)	49 CFR 173.465 (a), application (b), Water Spray (c), Free Drop (d), Stacking (e), Penetration 49 CFR 173.466 (a), additional tests (a)(1), Free Drop (a)(2), Penetration

49 CFR 173, *Shippers—General Requirements for Shipments and Packagings*

These regulatory requirements fall into two general categories: (1) requirements the test facilities should satisfy by review of documentation provided by the applicant, and (2) requirements the test facilities should satisfy by performing actual packaging tests. The following sections more fully describe the responsibilities of the test facilities in these two areas.

4.2.2.3.1 Documentation Review.

The package design as presented to a test facility should be documented in sufficient detail to enable a test facility to verify compliance with all the current 49 CFR design requirements. See Section 4.2.3 for details. The applicant is required to provide this documentation on the packaging qualification checklist included as part of the design packet.

A test facility should ensure the packaging qualification checklist covers all the current Type A packaging design requirements, including any which may have been established by DOE Order or management directive. It is the responsibility of each test facility to ensure that a packaging under its review complies with the latest regulatory and management requirements pertaining to Type A packaging, and not only to those which are documented in the packaging qualification checklist. Each test facility should notify EM whenever modifications to the DOT-7A Type A Packaging Qualification Checklist are needed.

Each test facility is required to review the procedures pertaining to proper loading, unloading, and other handling of the packaging as a part of the package design review in order to ensure that they fully document the required package handling. Further, the test facility should verify that the intended packaging contents for the packaging under review are in a form (e.g., non-dispersible solid, dispersible solid, liquid, or gas) suitable to the packaging. If intended radionuclide contents are specified in the packaging documentation, the test facility should verify that the intended contents are indeed Type A quantities. If evaluations of shielding and thermal load are provided by the applicant, the test facility reviewing the documentation should confirm the suitability of the packaging in both these areas. If a plastic packaging or receptacle is to be used to transport liquids, the test facility should perform the required testing of chemical compatibility, rate of permeation in plastic packagings and receptacles, and any gas generation by chemical reaction and radiolysis.

Each test facility should have staff on hand who are qualified to evaluate the documentation provided by the applicant.

4.2.2.3.2 Test Requirements.

Each test facility is responsible for performing the tests specified in 49 CFR 173.24(e)(3)(ii), 173.24a(a)(5), 173.412(f), and 173.465–466. Before these tests can be

performed, suitable surrogate contents should be selected, the packaging should be inspected for compliance with the documentation provided by the applicant (including examination of packaging components for damage) per 49 CFR 173.462, and the packaging should be loaded according to the procedure provided by the applicant. For the Type A tests of 49 CFR 173.465–466, compliance should be based on the assumption required in 49 CFR 173.461(b) with respect to the initial conditions of the package that the package is in equilibrium at an ambient temperature of 38°C (100°F). Each test facility should have one or more procedures in place describing how these activities will be performed.

For more detail describing the test facility requirements for Type A packaging tests and the respective pass/fail criteria for each test, see Attachment 4, *Capability of Test Facilities for Testing Type A Packagings*.

4.2.2.4 Quality Assurance.

DOE O 414.1C, *Quality Assurance*, June 17, 2005, establishes quality assurance requirements for DOE. This Order defines ten quality assurance criteria in three categories: management, performance, and assessment. Application of each of these areas to this program is discussed in Attachment 5, *Quality Assurance for Contractor Testing Facilities*.

4.2.3 Application for Packaging Approval.

The applicant who wishes to have a DOT Specification 7A Type A radioactive materials packaging tested and approved by the EM program (qualified to the specifications of 49 CFR 178.350) should perform the following steps:

a. Submit a written request to EM with the "need date," type of packaging, and contents specified.

b. Provide the packaging test facility with a test plan, a blueprint-like drawing of the container, design packet, representative loads (if requested), and any other materials necessary to perform the testing. After the tester determines how many units are needed, provide the appropriate number of prototype containers.

The procedural steps involved in obtaining a packaging approval are presented in Figure IV.2 of Section 4.2. In the listing above, Item b is the most involved step. The requested design packet consists of detailed drawings and specifications, an analysis report, documented operating instructions, and a completed packaging qualification checklist.

The qualification checklist addresses the characterization of the contents for compatibility with the selected packaging and details the following characteristics: (1) radiological, (2) activity limits, (3) thermal, (4) allowable contents (physical and chemical form), (5) packaging design (including shielding), (6) lifting and handling, tie down, and (7) quality assurance provisions.

A properly completed packaging qualification checklist would contain documentation that the applicant has addressed the following regulatory requirements:

178.350 Specification 7A; general packaging, Type A
173.21 Forbidden materials and packages
173.22 Shipper's responsibility
173.24 General requirements for packagings and packages
173.24a Additional general requirements for non-bulk packagings and packages
173.24b Additional general requirements for bulk packagings
173.410 General design requirements
173.412 Additional design requirements for Type A packages
173.415(a) Authorized Type A packages
173.441 Radiation level limitations
173.442 Thermal limitations
173.443 Contamination control
173.461 Demonstration of compliance with tests
173.462 Preparation of specimens for testing
173.463 Packaging and shielding—testing for integrity
173.465 Type A packaging tests
173.466 Additional tests for Type A packagings designed for liquids and gases
173.474 Quality control for construction of packaging
173.475 Quality control requirements prior to each shipment of radioactive materials

The applicant is required to provide a set of procedures describing the proper loading, unloading, and other handling of the packaging. Compliance must be demonstrated with the packaging structural requirements, including the lifting attachment requirements of 49 CFR 173.410(b) and the requirements for tie-down failure under excessive loads of 49 CFR 173.412(i).

Contents for the packaging under review should be in a form (e.g., non-dispersible solid, dispersible solid, liquid, or gas) suitable to the packaging. The applicant is not required to specify radionuclide contents; however, if intended radionuclide contents are specified in the packaging documentation, then the intended Type A contents should be provided or simulated. If the representative load is simulated, the physical properties of the test contents should be demonstrated to be equivalent to the working load. The representative load should be acceptable to EM and the test facility. If evaluations of shielding and thermal load are provided by the applicant, the test facility reviewing the documentation should confirm the suitability of the packaging in both these areas. Applicants using a plastic packaging or receptacle to transport liquids must fully describe, the liquid contents. This information is required by the test facility performing the required testing of chemical compatibility, rate of permeation in plastic packagings and receptacles and any gas generation by chemical reaction or radiolysis.

Any comments generated from the review of the documentation are provided to the applicant by the test facility and in normal circumstances should be resolved before testing is performed. For designs with satisfactory tests documentation is developed by the test facility. When the documentation of the packaging evaluation is approved by EM, the packaging is approved for use.

When a packaging is approved, EM provides the applicant with a copy of the approved test report for the packaging so the applicant may begin to use the packaging immediately.

For designs which do not pass the Type A tests, documentation of the reason for failure is provided to the applicant by EM. The applicant may then either, modify the design and have the packaging reevaluated and retested by the DOT-7A Testing Program or abandon the design effort.

4.2.4 Use of DOE-designed DOT Specification 7A Type A Radioactive Material Packagings.

The shipper and user must maintain on file the technical documentation of packagings qualified to the requirements of DOT-7A (49 CFR 178.350) and considered acceptable for transport of Type A quantities of radioactive material subject to the applicable restrictions and specifications.

The specific packaging data must meet the requirements of 49 CFR 173.415(a) for "...documentation of tests..." when the packagings are used as prescribed. In addition to

the documentation of tests, the user of the packaging must maintain on file other appropriate data applicable to the shipment, including (1) evaluation of the properties of the actual contents to be shipped for compatibility with the packaging and that their characteristics are bounded by the simulated contents used in qualification testing, and (2) the quality control program–and its implementation–developed to ensure the packaging materials, components, and arrangement are in accordance with the qualified design.

DOE-designed DOT Specification 7A Type A radioactive material packagings can consist of (1) steel drums, (2) steel boxes, (3) wooden boxes, (4) fiberboard containers, (5) UF_6 cylinders, (6) containers for liquids and gases, and (7) containers for specific contents. It is the user's responsibility to assure the packaging that he uses is still qualified and meets any necessary revisions.

Some alternative packages permissible for use are NRC-certified Type B packagings. In authorizing the use of NRC-certified packages for transportation of Type A quantities of radioactive material, DOT regulations specify, in 49 CFR 173.415, that certain conditions must be met. One condition (49 CFR 173.471) is that the shipment of the package be made in compliance with the terms of the NRC Certificate of Compliance. Alternatively, an NRC-certified package may be shipped under the provisions of 49 CFR 173.415(a) as a DOT-7A package. The same would be applicable for DOE certified Type B packagings.

4.3 Department of Energy Certified Type B and Fissile Packages

4.3.1 Responsibilities.

The flow of the documents for certification by EM of Type B or fissile packagings is as follows:

a. Contractor prepares the application for a Type B or fissile packaging including a Safety Analysis Report for Packaging (SARP) and submits all to the cognizant Field or Operations Office. Guidance for the application is found in Section 4.3.2.

b. The Field or Operations Office reviews the application for completeness and forwards it to the Secretarial Officer responsible for those facilities or activities requesting the certification.

c. The Secretarial Officer reviews the application and, if appropriate, forwards it to EM. The purpose of this review is for the responsible line management to: (1) be aware of the application, (2) determine that there is a need and adequate funding for the project,

and (3) declare the Office's support for the project.

d. On receipt of the application, EM establishes a docket for the application and assigns a review team to the project. When the review is completed, EM may issue a Certificate of Compliance if the review indicates that the design meets the standards of or is equivalent in safety to 10 CFR 71, as well as any special requirements that EM may determine applicable. The approved Certificate will return to the requestor through the same channels as received. Guidance for the review process is discussed in Section 4.3.3.

4.3.2 Safety Analysis Report for Packaging Preparation and Submission.

The SARP should be sufficiently detailed so as to permit the reviewer to determine that the package is designed and analyzed in sufficient detail and should document the adequacy of the packaging with respect to 10 CFR 71 standards or the equivalency thereto. These regulations state that a package must meet certain containment, radiation control, and subcriticality assurance requirements when subjected to specified normal transport and hypothetical accident conditions.

The SARP format preferred is described in NRC Regulatory Guide 7.9, *Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material*, March 2005. Additional guidance for SARP preparation may be found in other NRC Regulatory Guides and in the UCID-21218, *Packaging Review Guide for Reviewing Safety Analysis Reports for Packagings*, October 1999, including the March 2000 Interim Changes, or the ORNL/M-5003, *The Radioactive Materials Packaging Handbook* (Section 7, REFERENCES). Guidance and current details for submittal of the SARP are available on the RAMPAC website.

4.3.3 Review Process Guidance.

DOE O 460.1C requires that EM execute the certification program for the Department and the Headquarters Certifying Official come from EM. DOE O 460.1C defines the requirements for obtaining certification of packaging used by DOE and its contractors for Type B radioactive materials. Specific procedures are absent from DOE O 460.1C; instead, this Guide offers the established references for consultation to the reviewer for use in determination of the adequacy of the packaging design to meet the standards of NRC and any other applicable standards. Reasonable use of these references will maintain the quality and uniformity of the reviews.

4.3.4 Renewal of DOE Certificates of Compliance.

DOE certificates are issued for a specified period of time. The applicant (contractor) requesting the renewal should submit documentation to the Headquarters certifying official, through the appropriate field office, justifying renewal of the certificate. Such documentation should include (but not limited to):

a. The necessity for renewing the certificate;

b. That the SARP has been reviewed and complies with applicable requirements and standards; and

c. A summary usage history.

Documentation should be received by headquarters a minimum of 90 days prior to expiration of the certificate. DOE does not recognize the "Timely Renewal."

4.3.5 Use of Department of Energy Certified Packages.

DOE Field or Operations Offices and contractors may use any packaging whose design has been certified by the Headquarters Certifying Official provided the user meets the requirements specified in the Certificate, maintains the latest version of the complete SARP and Certificate of Compliance, and meets all other DOE packaging and transportation safety requirements in accord with DOE O 460.1C.

4.4 Use of Other Approved or Certified Packagings

DOE contractors may use any of the following in addition to the DOE approved packagings, as long as all regulatory requirements and any special provisions for the packagings are met.

4.4.1 Nuclear Regulatory Commission Certified Packaging.

If the contractor or DOE is registered as a user and the contractor possesses a copy of the latest NRC Certificate of Compliance and the packaging's SARP, the contractor may use an NRC certified packaging.

All requests for NRC Certificates of Compliance should follow the same process flow as for DOT Special Permits (Section 3).

4.4.2 Department of Transportation Specification Containers.

DOT Specification 6L, 6M, 20WC, and 21WC packagings may be used pursuant to the Hazardous Materials Regulations until 1 October 2008.

4.4.3 International Atomic Energy Agency (IAEA) Approvals.

DOT is the authorized agency to administer international approvals as the Competent Authority for the United States. Domestic shippers receive certification of the suitability and compliance of domestic packaging to foreign countries through DOT. This means any DOE or NRC certified packaging or DOT specification packaging must receive additional approval in the form of a U.S. Competent Authority Certificate for shipment into foreign countries. Copies of current U.S. Competent Authority Certificates covering the approval of packaging designs are sent prior to shipment to the Competent Authority of each country into or through which the packages will be transported. Foreign packaging of origin may be used only for import/export shipments when an IAEA certification has been issued and a U.S. (DOT) endorsement has been granted. This means a foreign national competent authority has certified the packaging's suitability and compliance and such certification have been validated by DOT. This validation or endorsement typically takes the form of a separate annex or supplement to the IAEA certification.

Additionally, radioactive material shipped as "special form" must have been first certified by a national competent authority as meeting the IAEA requirements for special form based on encapsulation or physical characteristics prior to any import or export shipments (49 CFR 173.476). DOT issues such certification for international shipments; domestic shipments do not have this requirement.

DOE contractors may use any international certification to which they or DOE are registered as a user, provided all requirements of the certification, special provisions, and other applicable regulations are met. New applications for Competent Authority approval or special form authorization should be submitted following the same process flow as for a DOT Special Permit (Section 3).

5. Onsite Transportation Safety Requirements

5.1 Introduction

The onsite portion of DOE O 460.1C (Paragraph 4.b) is based on the need in the DOE to have onsite transportation requirements in an Order. The Order mandates an Onsite Transportation Safety Document (TSD) for each site or facility in DOE. The TSD must comply with the "safe harbor" methods for safety analysis given in Appendix A to Subpart B of 10 CFR 830.

5.1.1 Purpose.

The purpose of this section is to provide guidance to DOE Field Offices and DOE contractors for implementation of the requirements of DOE O 460.1C, Paragraph 4.b, *Onsite Safety*.

5.1.2 Discussion.

The guidance provided herein supports the requirements of DOE O 460.1C. Responsibility for managing DOE hazardous material packaging and transportation activities in a safe and an environmentally sound manner resides with line management at DOE Headquarters, at each DOE Field Office, and within each DOE contractor organization.

In the performance of onsite packaging and transportation activities, assurance must be given that proper safety, health, and environmental protection are maintained. For onsite transfers of hazardous material at DOE sites, this assurance can be provided by specification of operational safety procedures in the site-specific TSDs. Adherence to federal regulations normally applicable to offsite transportation is an acceptable approach to meeting the onsite safety requirements. However, an alternative, integrated approach which considers the packaging in combination with specified communication and control measures is also acceptable.

Such an integrated approach should include hazard classification of the material, hazard containment, hazard communication, and control measures commensurate with the hazard of the material being transported, such as:

a. identification of the physical characteristics, chemical characteristics, and potential property damage of the designated hazard classification;

b. containment requirements for each hazardous material transfer that ensure retention of materials under normal onsite transport operations;

c. hazard communication requirements that provide sufficient information to personnel handling the material and to emergency responders, such that the hazards of the material being handled or transferred can be assessed prior to having direct contact with the material; and

d. control requirements appropriate for the level of containment and communication provided that take into account the possibility and consequences of credible accidents. These control requirements should result in minimal acceptance of risk above the risks accepted in the context of existing Hazardous Materials Regulations. For radioactive materials, appropriate controls also need to be provided to ensure nuclear criticality safety and minimize personnel exposures in accordance with As Low as Reasonably Achievable (ALARA) principles.

5.2 Guidance to Responsibilities

5.2.1 Operations Office and Field Office Managers.

In accordance with DOE O 460.1C, Paragraph 5. b, Heads of Operations Offices or Field Offices shall implement the requirements of this Order and ensure contractors under their purview fully implement and comply with the requirements of the Order. Responsibility specified for implementation of the onsite requirements is review and approval of transportation safety documents.

5.2.2 Contractor Management.

Contractor Management should ensure, for onsite transfers of hazardous materials, the Hazardous Materials Regulations are complied with or that an approved site- or facility-specific TSD meeting equivalent safety requirements is followed. Contractor management should ensure that a site- or facility-specific TSD exists which satisfies Section 5.3 of this *Guide* and is updated and maintained.

5.3 Preparation of Transportation Safety Documents

5.3.1 Introduction.

DOE O 460.1C requires that deviations from the Hazardous Materials Regulations of DOT for onsite transfers be documented in an approved site-specific TSD. This document

describes (explicitly or by reference) the methodology and compliance process to meet equivalent safety measures relative to deviations from the Hazardous Materials Regulations. This TSD is expected to include:

a. identification of responsibilities, lines of authority, and program approval procedures;

b. definition of minimum safe packaging requirements including necessary design, fabrication, and quality assurance elements, using appropriate codes and standards;

c. description of transportation systems and operational controls utilized to restrict personnel and public access and minimize the probability and consequence of credible accidents;

d. a description of the process and analysis is used to ensure that equivalent safety requirements are established. This should include a technically justified basis for equivalency. For example, this could include a hazard analysis associated with the transfer, an assessment of the risks associated with the transfer, and a discussion of the mitigating measures proposed to ensure the equivalent safety requirements will be employed. This analysis would be performed for each deviation from the Hazardous Materials Regulations;

e. site description, including maps identifying boundaries, railways, and roadways, which clearly delineates offsite and onsite areas, and procedures for clearing and establishing access control for any area having occasional public access;

f. provisions for effective emergency response and recovery under credible accident conditions; and

g. process for accomplishing nonroutine packaging and transportation activities.

DOE O 460.1C requires each TSD be approved by the cognizant DOE Field Office. Approval shall constitute acceptance of the site program as meeting DOE transportation safety requirements. DOE O 460.1C states an approved Transportation Safety Documents shall be in effect no later than one year from incorporation of this Order into contractor contracts and all onsite transfers shall comply with either the Hazardous Materials Regulations or an approved TSD.

5.3.2 Format for Transportation Safety Documents.

Following is the preferred format for the TSDs. The level of detail required in each TSD is dependent on the complexity of operations, demographic conditions at the site, quantities and types of materials being transported, number and complexity of site transport routes, and need for special controls (including safeguard controls) to meet DOE transportation

safety requirements.

Sites with a well-developed TSD do not need to rewrite their document to this format; instead, they may provide a crosswalk from the existing format to this one and add relevant sections where needed.

a. Chapter I. *Purpose, Scope and Applicability*

Purpose. The purpose should state that the TSD documents the onsite packaging and transportation program and demonstrates its compliance with DOE transportation safety requirements.

Scope. The scope should state that the TSD covers all transfers of hazardous materials, substances and wastes. Although the term "transfer" refers only to onsite transportation of hazardous materials, readers not familiar with this definition may find a statement of this definition helpful at this point.

Applicability. The applicability statement should describe how the requirements of the document are applied to site and facility operations. It should be written so that someone needing to move hazardous material can understand whether or not the requirements of the document apply to the movement in question. This section should also state who is responsible for control of document distribution and for preparation and distribution of document updates. In addition, it should explain how controlled distribution and maintenance of the document will be accomplished.

b. Chapter II. *Definitions and Acronyms*

Definitions and Acronyms. This section should define all terms or acronyms used in the TSD which are relevant to onsite packaging and transportation operations. Site-specific terms should be defined for the benefit of new employees or external reviewers of the document.

c. Chapter III. *Site Description*

Maps. This section identifies the physical location of the site and associated facilities on legible maps. Site boundaries should be clearly marked. Fences and other restrictions to public access should be identified. All features of the site mentioned in the document, such

as facilities, buildings, entryways, storage areas, transport routes, and transportation hazards, should be clearly identified on one or more maps, and the appropriate maps should be referenced when site-specific features are mentioned in the text. The goal of this section should be to provide enough information to enable a reader unfamiliar with the site (such as a new employee or an independent reviewer) to comprehend all site-specific discussion in the TSD.

Vehicles. A list should be provided of the transport vehicles used for onsite hazardous materials movements or reference to the location of such listing.

d. Chapter IV. *Organizational Responsibilities*

This chapter should describe the packaging and transportation organizational structure within the framework of the entire site organization. Organization charts are encouraged for clarity. The authority and responsibilities of principal organizations and key positions within those organizations should be clearly described, so that lines of authority and reporting may be understood. Independence of oversight organizations should be demonstrated. Program approval procedures should be cited.

e. Chapter V. *External Regulations*

This chapter should reference the principal Federal, State, and local regulations, DOE Orders, and other requirements affecting onsite packaging and transportation activities which have been imposed by organizations external to the site organization. It should provide a complete picture of all the externally-imposed requirements with which the onsite packaging and transportation activities must comply. It should also identify any Government and industrial standards used as benchmarks in the development of the onsite packaging and transportation program.

f. Chapter VI. *Site-Specific Standards, Procedures, and Instructions*

This chapter should identify the site-specific standards, procedures, and instructions applicable to onsite packaging and transportation activities. This section should only present the general requirements governing the development of specific procedures for individual hazardous material transport activities. Any packaging standards, performance criteria, and design, fabrication, and quality elements identified in this chapter should be supported by applicable codes and standards. Site-wide procedures for subjects such as

securing of loads and tie-downs, load compatibility, contamination and radiation exposure control, and criticality control should be identified and/or referenced. All relevant site policy and procedures Documents (e.g., radiological protection manuals and health and safety manuals) should be referenced.

g. Chapter VII. *Safety Assessment Methodology*

This chapter should provide a description of the methodology used to achieve and demonstrate compliance with DOE O 460.1C, Paragraph 4.b. The description of the methodology should include a description of any problematic or risk-based approaches used.

Guidance on developing and applying a safety assessment methodology is provided in Section 5.4 of this document. This guidance recommends development of a hazardous materials hierarchy and associated performance requirements and documentation of these requirements in this chapter. In developing an onsite packaging and transportation system for hazardous materials, it is recommended that the primary emphasis be placed on packaging design and packaging performance to ensure containment of materials during normal onsite transfer activities. A well-designed packaging can lessen both the probability and the consequences of a hazardous material release for a given package handling scenario.

h. Chapter VIII. *Routine Transfers*

This chapter should identify the major categories of hazardous materials or hazard classes routinely transferred onsite, the packagings used for each, and the specific procedures followed. The procedures may cover such topics as identification and classification of material, packaging selection, packaging preparation and use, transport vehicle scheduling and use, hazard communication, hazard control, and routine approvals.

i. Chapter IX. *Non-Routine Transfers*

This chapter should present the procedures for processing and approving a request for an exception to the routine transfer requirements of Chapter VIII. These procedures should address the required format, content and control of this type of request, conditions under which approvals should be sought and given, approval authorities, maintenance of documentation, period of approval, and exclusions.

Except under emergency conditions, approval should only be granted after the proposed transfer has been formally demonstrated in a safety assessment.

j. Chapter X. *Personnel Qualification and Training*

This chapter should define or reference the training requirements for personnel involved with (onsite) hazardous material packaging and transportation activities. It should identify required courses, course content, testing, and qualification requirements for various packaging and transportation personnel as a function of the jobs to be performed. Documentation of training, qualification, and recertification should be specified.

k. Chapter XI. *Documentation and Record Keeping*

This chapter should identify all site-specific documentation to be maintained to support the onsite transportation safety program. The records requirements should include retention of such items as packaging documentation (e.g., SARPs, test reports, or other packaging evaluations), personnel training and qualification records, vehicle maintenance and inspection records, and documentation associated with both routine and nonroutine transfers. This chapter should specify what records must be maintained, who is responsible for maintaining the records, how the records are to be stored, and how long the records are to be retained.

l. Chapter XII. *Incident Reporting and Emergency Response*

This chapter should describe the incident reporting and emergency response plans for the site. The lines of communication and the roles and responsibilities of key personnel involved in an emergency response or incident report should be presented. Relevant procedures may be referenced. Planning should be adequate to cover all credible emergency situations to ensure effective response and recovery after a transport accident or incident.

m. Chapter XIII. *Transport Vehicle Operations*

This chapter should identify or reference maintenance and inspection requirements and associated procedures for onsite vehicles. It should identify routine operator duties and procedures.

n. Appendices and Other Pertinent Information

This section can include additional site specific guidance to assist transport operations such as:

- Examples of labels, markings, placards
- Site material transfer documents (shipping papers)
- Lists of packagings (packaging directory)
- Maps (roads, railways, site boundaries, facilities, crossings, adjacent streams, waterways and wetlands)
- Incident reporting forms
- Vehicle maintenance forms
- Other forms

5.4 Safety Assessment Methodology

5.4.1 Use of a Graded Approach.

DOT regulations are structured so that materials representing a greater hazard are subject to greater containment, communication, and control requirements. DOT regulations may be applied to onsite transfers to ensure compliance with the Order. Where DOT regulations are not used to ensure compliance with the Order for onsite movements, a graded approach to compliance may be established.

A site seeking to establish a graded approach to compliance with DOE O 460.1C should develop a hierarchy grouping hazardous materials into a series of hazard levels. For each hazard level, the performance requirements for the transport system (where the transport system consists of the packaging plus the controls and communication requirements imposed on its transport) should then be established. The performance requirements imposed on each hazard level in the hazardous materials hierarchy should be documented in Chapter VII of the TSD. This documentation should enable a site to establish containment, control, and communication requirements for onsite movements in a consistent and justifiable manner, and should ensure that requirements established for an onsite movement will be commensurate with the hazard of the material being transported.

5.4.2 Safety Assessment.

Reliance on packaging performance is a preferred way to ensure overall safety; however,

an integrated approach considering the packaging in combination with specified communication and control measures is also acceptable.

Figure IV.3 presents the options available to a site for complying with DOE O 460.1C, and indicates the evaluations needed to support each. As a first step, the packaging should be placed into one of three categories: (1) DOT packaging, (2) equivalent packaging, or (3) non-equivalent packaging. DOT packaging is packaging meeting the regulations of DOT for offsite shipment of the hazardous material to be transported onsite. Equivalent packaging is packaging providing documented performance equivalent to packaging meeting the requirements of DOT for offsite shipment. Packaging falling into this category will generally be a slight modification of a DOT packaging. Non-equivalent packaging is any packaging not demonstrated to be either DOT or equivalent packaging. As the figure shows, DOT packaging requires no special evaluation. It need only be documented as approved packaging. Equivalent packaging should be supported by a documented evaluation where equivalence is formally established. Once established, equivalent packaging may be used interchangeably with DOT packaging for onsite movements.

Still following the logic of Figure IV.3, DOT and equivalent packagings may be used onsite in two ways. First, they may be used in compliance with all DOT control and communication requirements for offsite movements. The use of full DOT control and communication requirements should be documented in the TSD. No further evaluation is then required.

Second, these packagings may be used with site-specific control and communication requirements. To ensure that DOE O 460.1C is met, the site-specific requirements should be evaluated to demonstrate that (1) transport conditions provided by the onsite controls are no more severe than would be encountered by a package being transported offsite and (2) personnel potentially involved with the transport and emergency response teams receive adequate communication regarding the hazards involved with the transport. The final option represented in Figure IV.3 involves the use of non-equivalent packaging. Because this packaging has not been demonstrated to function equivalently to DOT packaging, the use of full DOT control and communication requirements may not be adequate for this type of packaging.

Before non-equivalent packaging may be used for onsite transport, a performance envelope should be established for the packaging and specific control and communication requirements should be developed to ensure the transport system will operate safely within the performance envelope.

The evaluation of the transport system described in Figure IV.3 should take the form of a safety assessment. The safety assessment may be straightforward or very complex, depending primarily on the packaging to be used for the hazardous materials movement. As a first step, the packaging should be evaluated and placed into one of the three categories described earlier: (1) DOT packaging, (2) equivalent packaging, or (3) non-equivalent packaging. The details of the required evaluation then follow from Figure IV.3.

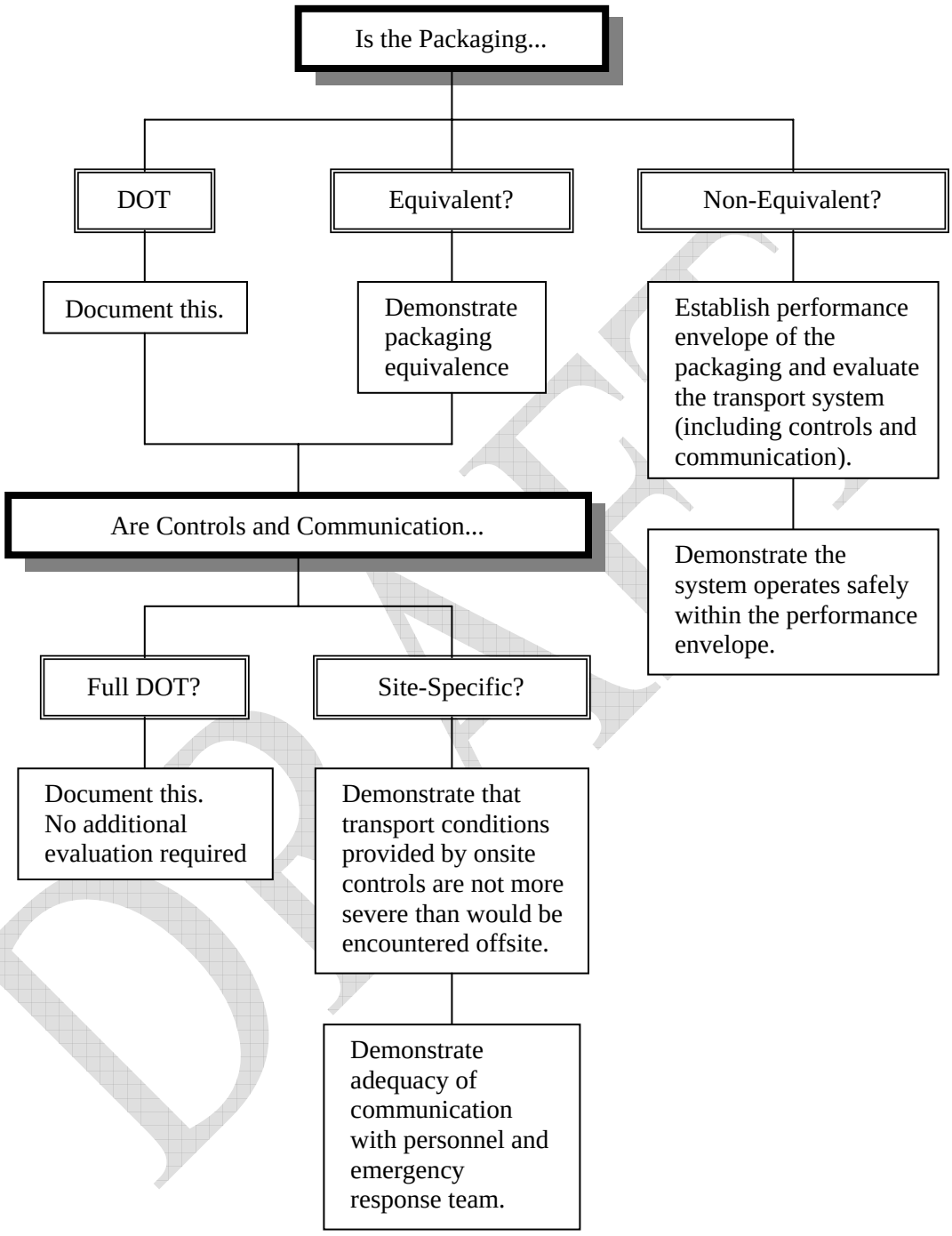

Figure IV.3 Available Options for Complying with DOE O 460.1C.

The safety assessments for routine onsite hazardous materials movements may be documented in Chapter VIII of the TSD or as stand-alone documents referenced in Chapter VIII. The process how safety assessments for nonroutine transfers are performed, documented, and approved should be described in Chapter IX of the TSD. Documentation of the safety assessment may cover the following topics:

a. Description. The onsite hazardous material movement to be evaluated should be thoroughly described. The hazardous material to be transported should be stated, and its hazard level should be indicated. Site-specific details, such as transport routes, should be described where appropriate.

b. Packaging. The packaging to be used for the onsite transfer should be described, and should be categorized as (1) DOT packaging, (2) equivalent packaging, or (3) non-equivalent packaging. For DOT packaging, the safety assessment documentation should reference the appropriate DOT standard and any packaging test report or other documentation demonstrating the packaging is approved for offsite shipment of the hazardous material to be transported onsite. For equivalent packaging, the safety assessment documentation should provide a reference to the equivalent DOT packaging and should provide supporting evidence to demonstrate equivalence. For non-equivalent packaging, the safety assessment documentation should provide a detailed analysis of the packaging clearly establishing the performance envelope of the packaging. To establish the performance envelope of the packaging, evaluation of design basis conditions (DBCs) is recommended. DBCs should be site-specific, and possibly route-specific, conditions where the packaging should be able to provide containment during onsite transport. DBCs to be considered for a particular hazardous materials transport will depend on the hazard level of the material. Chapter VII of the TSD should include guidance on which DBCs should be developed for each hazard level, and should establish minimum performance requirements for each hazard level. Examples of DBCs which may be appropriate for some hazard levels are shock, vibration, collision, fall, fire, penetration, and immersion. Others may also be appropriate.

   To illustrate how the performance requirements established in Chapter VII of the TSD can be used to develop an appropriate DBC, a particular hazardous material may be grouped into a hazard level that requires a packaging to be able to survive a 3-ft drop with no loss of containment. For this hazardous material, a 3-ft drop would then become the DBC for falls, without regard to conditions along the transport route or during handling which might expose the packaging to a fall from a higher distance. If the packaging could not survive a 3-ft drop, additional administrative controls would need to be imposed on the transport system to ensure an adequate level of safety during transport. Guidance regarding appropriate administrative controls should be provided in Chapter VII of the TSD.

   As an example of how physical limitations of a site may be incorporated into a DBC, a particular hazardous material may be grouped into a hazard level that requires a packaging to be able to survive a 30-ft drop. For this particular hazardous material shipment, an evaluation of the transport route may show that, for any accident which

could occur along the transport route, the packaging could never fall more than 10 ft. If a control on the packaging is also imposed requiring that the packaging never be elevated more than 10 ft during handling, the DBC need only consider a 10-ft fall.

c. Controls. The controls to be placed on the onsite hazardous materials transport should be described. As shown in Figure IV.3, full compliance with DOT control and communication requirements for offsite transport is an option, unless a non-equivalent packaging is being used. The full compliance option may be documented with no further evaluation. (The tie down and vehicle requirements of DOT would need to be imposed for a hazardous materials transport to be in full compliance with offsite DOT regulations.) For DOT or equivalent packaging, the other option is to provide site-specific controls. These controls need only ensure the packaging will not be exposed to transport conditions any more severe than the packaging would experience during an offsite shipment.

For non-equivalent packaging, controls should be commensurate with the hazard represented by the package being transported, and should ensure the packaging operates within its established performance envelope. The hazard levels and associated performance requirements documented in Chapter VII of the TSD will greatly facilitate development and justification of appropriate transport controls. Controls may include establishment of special communication requirements (e.g., radio contact with emergency response personnel) which are required to compensate for packaging inadequacies.

d. Communication. The communication requirements for the onsite hazardous material transport should be described. Again, Figure IV.3 shows that full compliance with DOT communication and control requirements for offsite transport is an option for DOT and equivalent packaging. This option may be documented with no further evaluation. Full DOT compliance would include strict adherence to use of DOT packaging as well as all marking, labeling, placarding, and shipping papers requirements of DOT. The other option for DOT and equivalent packaging is to develop site-specific communication requirements. Since the purpose of the DOT marking, labeling, placarding and shipping papers requirements is to communicate the hazards of the material being shipped to personnel handling the material and to emergency responders in the event of an accident, sites may develop other methods of communication with personnel involved with the transport and with emergency response personnel.

For non-equivalent packaging, communication requirements need to be established and evaluated as part of the entire transport system. The system should be shown to provide equivalent safety.

As with the establishment of all transport requirements, communication requirements should be commensurate with the hazard of the material being transported. Justification for communication requirements can best be provided on the basis of the performance requirements documented in Chapter VII of the TSD.

In some cases, special communication requirements will be described as part of the control requirements for the transport. Such requirements should be repeated here.

e. Conclusion. The safety assessment should conclude, based on the evidence provided, the transport system provides a level of protection commensurate with the hazard of the material being transported.

6. Quality Assurance

The Quality Assurance Chapter of the SARP describes QA requirements for fissile material and Type B RAM packagings that apply to design, procurement, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair and modification of packaging components important to safety. The applicant for a CoC is responsible for specifying packaging specific QA requirements for a SARP in the QA chapter.

The applicant for a fissile or Type B packagings CoC are required to establish, maintain, and implement a QA program in compliance with Subpart H, 10 CFR Part 71, *Quality Assurance*, containing eighteen quality assurance (QA) elements. Department of Energy (DOE) nuclear facilities are required to meet 10 CFR 830 Subpart A, *Quality Assurance Requirements* (otherwise known as the "QA Rule") and DOE O 414.1C, *Quality Assurance*. The ten QA criteria of these of these two documents are essentially identical. Most existing DOE applicant QA programs are based on the ten criteria. Title 49 CFR Part 173.7(d) and DOE O 460.1C require the DOE to evaluate, approve, and certify packages according to the standards equivalent to those used by the NRC. An applicant for a DOE CoC, certificate holder, or user of a certified packaging shall have a QA program in compliance with the 18 QA requirements specified in Subpart H of 10 CFR Part 71. The NRC also requires the licensees, certificate holders, and an applicant for a CoC establish, maintain and implement a QA Program as in Subpart H of 10 CFR Part 71. A Subpart H of 10 CFR Part 71 complaint QA program by a DOE applicant for a CoC or a DOE certificate holder demonstrates the required equivalency with the NRC concerning QA requirements for fissile material and Type B RAM packagings. 10 CFR 830 Subpart A/DOE O 414.1C states to use consensus standards, where practicable and consistent with contractual and regulatory requirements, in implementing the QA Rule/DOE Order. ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications*, is the recommended standard for nuclear-related applications. The eighteen elements of NQA-1 are essentially equivalent to the eighteen elements of 10 CFR 71 Subpart H, although the Nuclear Regulatory Commission (NRC) endorses only the 1983 and 1994 versions.

6.1 Graded Approach

Materials and components of packagings are to be designed, procured, fabricated, assembled and tested using a graded approach under a 10 CFR 71 Subpart H QA Program. Under that program, the categories critical to safety are established for all packaging components. These defined quality categories consider the impact to safety if the component were to fail or perform outside of design parameters.

The design, procurement, fabrication, assembly, testing, and use are conducted by DOE, its contractors or its suppliers, using a graded approach in accordance with NRC Regulatory Guide (RG) 7.10 and NUREG/CR-6407 as follows:

Graded Quality Category A Items:

These items and services are critical to safe operation and include systems, structures and components whose failure could directly result in a condition adversely affecting public health and safety. The failure of a single item could cause loss of primary containment leading to a release of radioactive material beyond regulatory requirements, loss of shielding beyond regulatory requirements, or unsafe geometry compromising criticality control.

Graded Quality Category B Items:

These items and services have a major impact on safety and include systems, structures and components whose failure or malfunction could indirectly result in a condition adversely affecting public health and safety. The failure of a Category B item, in conjunction with the failure of an additional item, could result in an unsafe condition.

Graded Quality Category C Items:

These items and services have a minor impact on safety and include systems, structures and components whose failure or malfunction would not significantly reduce the packaging effectiveness and would not be likely to create a situation adversely affecting public health and safety.

Table IV.4 Safety Assessment of Packaging Features Example

Q Category	Quality Item	Basis for Designation	Drawing Number
A	Vessel Weldment	Containment	Z-R3-A-0008-A
A	Cone-Seal Plug	Containment	Z-R4-A-0001-A
A	Cone-Seal Nut	Containment	Z-R4-A-0001-B
A	Outer O-ring	Provides means for post-load leak rate test and redundancy for inner O-Ring (see Tablenote 1)	Commercial Grade Dedication
A	Inner O-ring	Containment	Commercial Grade Dedication
B	Gland Nut Plug Assembly	Containment	Z-R4-A-0002-F
C	Dunnage	Non-Safety function	Commercial
Non-Q	Retaining Ring	Non-safety function	Commercial
Non-Q	Screw	Non-Safety Function	Commercial
Non-Q	Alternate Support Pedestal	Non-Safety Function	Z-R4-A-0002-D
Non-Q	Handling Socket	Non-Safety Function	Z-R4-A-0000-A
Non-Q	Lower Support Pedestal Assembly	Non-Safety Function	Z-R4-A-0002-C

1. The outer O-ring is not needed for containment, but is classified as Category A because it is the same specification as the inner O-ring. This will simplify O-ring procurement and will prevent mixing up replacement inner and outer O-rings.

Table IV.5 Typical Level of QA Effort by Quality Category for Package Activities

QA Element/Level of Effort	Category A	Category B	Category C
1. QA Organization			
Responsibility established	X	X	X
Authority and duties written	X	X	X
QA functions executed	X	X	X
Reporting levels clearly defined	X	X	X
Independence from cost and schedule assured	X	X	X
Independence of quality achievers vs. verifiers	X	X	X
2. QA Program			
Procedures written	X	X	X
Activities affecting quality controlled	X	X	X
Graded approach established	X	X	X
Indoctrination and training provided	X	X	X
3. Package Design Control			
Most stringent codes and standards	X		
Codes and standards		X	
Prototype test and/or analysis	X	X	
Formal design review (Independent for Cat A&B)	X	X	
Internal peer review	X	X	
Software QA	X	X	
Off-the-shelf items			X
Conditions of approval controlled	X	X	X
4. Procurement Document Control			
Traceability	X	X	
Qualified vendor lists	X		
Suppliers required to meet Subpart H	X	X	
Off-the-shelf items			X
5. Instructions, Procedures, and Drawings			
Written and documented	X	X	
Qualitative or quantitative acceptance criteria	X	X	
Changes to conditions of approval listed in certificate controlled	X	X	X

Table IV.5 Typical Level of QA Effort by Quality Category… (cont.)

QA Element/Level of Effort	Category A	Category B	Category C
6. Document Control			
Controlled issue	X	X	
Controlled changes	X	X	
7. Control of Purchased Material, Equipment, and Services			
Source evaluation and selection	X		
Inspection at contractor	X		
Formal receiving inspection	X	X	
Audits or surveillance at vendor plants	X		
Evidence of QA at contractor	X	X	
Objective proof that all specifications are met	X	X	
Commercial grade item/services dedication	X	X	
Incoming inspection for damage only			X
8. Identification and Control of Materials, Parts, and Components			
Positive identification and traceability	X		
Identification and traceability to heats, lots, or other groupings	X	X	
Identification to end use drawings			X
9. Control of Special Processes			
Welding, heat treating, and NDE performed with qualified/certified personnel and procedures	X	X	
Qualification records and training of personnel	X	X	
Only specified critical operations by qualified personnel		X	
No special processes			X
10. Internal Inspection			
Documented inspection of all specifications	X		
Process monitoring if required by quality	X		
Examination, measurement, or test of material or processed product to assure quality	X	X	
Inspectors independent of those performing operations	X	X	
Qualified inspectors only	X	X	
Visual receiving inspection only			X

Table IV.5 Typical Level of QA Effort by Quality Category… (cont.)

QA Element/Level of Effort	Category A	Category B	Category C
11. Test Control			
Written test program	X	X	
Written test procedures	X	X	
Documentation of testing and evaluation	X	X	
Observation of supplier acceptance tests as appropriate	X		
Validate computer programs, computer hardware, and operating system	X	X	
12. Control of Measuring and Test Equipment			
Tools, gauges, and instruments in formal calibration program	X	X	
13. Handling, Storage, and Shipping Control			
Written plans and procedures	X	X	
Routine handling			X
14. Inspection, Test, and Operating Status			
Individual items identified as to status or condition	X	X	
Status indicated by stamps, tags, labels, etc.	X	X	
Visual examination only			X
15. Nonconforming Materials, Parts, or Components			
Written procedures to prevent inadvertent use	X	X	X
Nonconformance documented and closed	X	X	X
Disposal (scrap) without records			X
16. Corrective Action			
Conditions adverse to quality identified and corrected	X	X	X
Cause and corrective action documented	X	X	
Safety significant events reported	X	X	X

Table IV.5 Typical Level of QA Effort by Quality Category… (cont.)

QA Element/Level of Effort	Category A	Category B	Category C
17. QA Records			
Design and use records	X	X	
Results of reviews, inspections, tests, audits, surveillances, and materials analysis	X	X	
Personnel qualifications	X	X	
Records of design, fabrication, acceptance testing, and maintenance retained for life of package plus 3 years	X	X	
Shipping records retained for 3 years after shipment	X	X	X
Records managed by a written procedure for retention and disposal	X	X	X
18. Audits			
Written plan of periodic audits	X	X	X
Implementation by written procedures	X	X	X
Lead auditor qualified	X	X	
All auditors qualified	X		

Upon custodianship of the packaging by DOE or an operating contractor, the site functional classifications will be used for the site operations and activities related to the packaging. The method of classification can be documented in a site QAPP, as follows.

For the purposes of DOE Order 460.1C, *Packaging and Transportation Safety*, SARPs are the PSSD. As appropriate, the hazard analysis and accident scenarios in the safety basis documents (DSA or PSSDs, etc.) help identify SSCs that must function in order to prevent or mitigate these events. These SSCs are then identified in the applicable PSSD using the classification system found in the NRC QA Category system provided in RG 7.10 or in the TSD. The categories as defined in RG 7.10, and listed below, are analogous to Safety Class, Safety Significant and General Service that are identified for facility SSCs.

Quality Category A:

Critical impact on safety and associated functional requirements: items or components whose single failure or malfunction could directly result in an unacceptable condition of containment, shielding, or nuclear criticality control. This is functionally equivalent to

"safety class" designation used for nuclear facility safety.

Quality Category B:

Impact on safety and associated functional requirement: components whose failure or malfunction in conjunction with one other independent failure or malfunction could result in an unacceptable condition of containment, shielding, or nuclear criticality control. This is functionally equivalent to "safety significant" designation used for nuclear facility safety.

Quality Category C:

Minor impact on safety and associated functional requirements: components whose failure or malfunction would not result in an unacceptable condition of containment, shielding, or nuclear criticality control regardless of other single failures. This is functionally equivalent to designations given to components that do not meet "safety class" or "safety significant" criteria used for nuclear facility safety.

The packaging Design Authority (DA) identifies critical characteristics when identifying design attributes necessary to preserve the safety support function. As necessary, the DA also ensures critical characteristics are included in a SAR by the identification of SSCs and their QA Category designations. Additionally, a SAR shall include the safety function, design, and operational attributes necessary for reliable performance. The DA applies design criteria to the design, operation and maintenance of each critical SSC including recommended codes and standards, as required by RG 7.10. QA requirements shall be applied as necessary to assure the SSCs can perform their function.

In general, a QA program developed under the ten criteria of 10 CFR 830 Subpart A/DOE O 414.1C will require supplementation in order to meet the requirements of 10 CFR 71 Subpart H. In comparison, the requirements of 10 CFR Subpart H are more prescriptive and rigorous than the ten criteria, which are basic, performance based QA requirements. Supplementation can be included in the QA plan and implementing procedures that define the applicant's QA program. Chapter 9 of the Safety Analysis Report for Packaging (SARP) must address the eighteen elements of 10 CFR 71 Subpart H. Since Chapter 9 is a description of the applicant's QA program (it is not the actual QA program) it should not contain information that is not already documented in the actual QA program defined by QA plan(s) and implementing procedures. Chapter 9 should also not merely be a

restatement of the eighteen elements, but should include details on how the QA requirements are being met by the QA program.

ANSI/ISO/ASQ Q9001-2000, *Quality management systems–Requirements* is another QA standard commonly and increasingly used by suppliers. ISO 9001 also requires supplementation in order to meet 10 CFR 71 Subpart H. ASME NQA-1-2004, Subpart 4.3, *Guide to Modification of an ISO 9001-2000 Quality Program to Meet NQA-1-2000 Requirements* provides a detailed comparison of the two documents and a gap analysis. The NRC, in *Approaches for Adopting More Widely Accepted International Quality Standards*, SECY-03-0117, provides a detailed gap analysis between ISO 9001 and 10 CFR 50 Appendix B (a regulation virtually equivalent to 10 CFR 71 Subpart H). Supplementary QA requirements must be included in purchase orders to ISO 9001 suppliers to meet 10 CFR 71 Subpart H requirements.

6.2 Comparison and GAP Analysis 18-Point to 10-Point QA Programs

The following is a comparison and gap analysis of 10 CFR to 10 CFR 830 Subpart A/DOE O 414.1C. This comparison can be used as guidance in adapting an existing 10 CFR 830 Subpart A/DOE O 414.1C QA program to meet 10 CFR 71 Subpart H. This comparison does not include the five DOE QA guides. The guides provide non-mandatory guidance in implementing the QA Rule/DOE Order.

In general, the eighteen elements of 10 CFR 71 Subpart H are more prescriptive and rigorous than the ten criteria of 10 CFR 830 Subpart A/DOE O 414.1C. Chapter 9 of the SARP should be responsive to all eighteen elements of 10 CFR 71 Subpart H. If the QA program described in Chapter 9 is based solely on the QA Rule/DOE Order, then that QA program will need to be augmented. This comparison matrix is provided as a tool in determining the supplementation required.

Table IV.6 Comparison of 10-Point- and 18-Point Programs

10 CFR 71 Subpart H Requirement	10 CFR 830 Subpart A/ DOE O 414.1C Criteria	Comments/Gap Analysis
71.103 – QA Organization (a) The licensee, certificate holder, and applicant for a CoC shall be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions. (b) The quality assurance functions are-- (1) Assuring that an appropriate quality assurance program is established and effectively executed; and (2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed. (c) The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to-- (1) Identify quality problems; (2) Initiate, recommend, or provide solutions; and (3) Verify implementation of solutions. (d) The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided. (e) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the	1 – Management/ Program (1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. 6 – Performance/ Design (4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work. 10 – Assessment/ Independent Assessment (1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. (2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments. 9 – Assessment/ Management Assessment Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.	The QA program may need to be supplemented to ensure that the degree of independence, authority, and access to management is adequate for personnel performing QA functions in order to meet the requirements of this section of 10 CFR 71 Subpart H.

10 CFR 71 Subpart H Requirement	10 CFR 830 Subpart A/ DOE O 414.1C Criteria	Comments/Gap Analysis
required authority and organizational freedom. (f) Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.		
71.105 – QA Program (a) The licensee, certificate holder, and applicant for a CoC shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of §§ 71.101 through 71.137. The licensee, certificate holder, and applicant for a CoC shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee, certificate holder, and applicant for a CoC shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations. (b) The licensee, certificate holder, and applicant for a CoC, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee, certificate holder, and applicant for a CoC shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee, certificate holder, and applicant for a CoC shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test. (c) The licensee, certificate holder, and	830.121 Quality Assurance Program (a) Contractors conducting activities, including providing items or services, that affect, or may affect, the nuclear safety of DOE nuclear facilities must conduct work in accordance with the Quality Assurance criteria in § 830.122. (b) The contractor responsible for a DOE nuclear facility must: (1) Submit a QAP to DOE for approval and regard the QAP as approved 90 days after submittal, unless it is approved or rejected by DOE at an earlier date. (2) Modify the QAP as directed by DOE. (3) Annually submit any changes to the DOE-approved QAP to DOE for approval. Justify in the submittal why the changes continue to satisfy the quality assurance requirements. (4) Conduct work in accordance with the QAP. (c) The QAP must: (1) Describe how the quality assurance criteria of § 830.122 are satisfied. (2) Integrate the quality assurance criteria with the Safety Management System, or describe how the quality assurance criteria apply to the	Essentially equivalent except that 10 CFR 71 Subpart H has additional specificity on the impact/risk of failure of materials and components on safety. This has been translated into the requirement for a Q-list of packaging structures, systems, and components; and the grading of QA effort as to the Q-category, as per NRC Reg Guide 7.10 [15] and Chapter 9 of the DOE Packaging and Review Guide [16].

10 CFR 71 Subpart H Requirement	10 CFR 830 Subpart A/ DOE O 414.1C Criteria	Comments/Gap Analysis
applicant for a CoC shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components: (1) The impact of malfunction or failure of the item to safety; (2) The design and fabrication complexity or uniqueness of the item; (3) The need for special controls and surveillance over processes and equipment; (4) The degree to which functional compliance can be demonstrated by inspection or test; and (5) The quality history and degree of standardization of the item. (d) The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.	Safety Management System. (3) Use voluntary consensus standards in its development and implementation, where practicable and consistent with contractual and regulatory requirements, and identify the standards used. (4) Describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the criteria of § 830.122. 2 – Management/Personnel Training and Qualification (1) Train and qualify personnel to be capable of performing their assigned work. (2) Provide continuing training to personnel to maintain their job proficiency. 9 – Assessment/ Management Assessment Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives. 10 – Assessment/ Independent Assessment (1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. (2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments. (3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in	

10 CFR 71 Subpart H Requirement	10 CFR 830 Subpart A/ DOE O 414.1C Criteria	Comments/Gap Analysis
	the areas to be assessed.	
71.107 – Package Design Control (a) The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that applicable regulatory requirements and the package design, as specified in the license or CoC for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important to safety. (b) The licensee, certificate holder, and applicant for a CoC shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures, among participating design organizations, for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design, by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee, certificate holder, and applicant for a CoC shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee, certificate holder, and applicant for a CoC shall apply design control measures to the following: (1) Criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses; (2) Compatibility of materials; (3) Accessibility for inservice inspection,	6 – Performance/Design (1) Design items and processes using sound engineering/scientific principles and appropriate standards. (2) Incorporate applicable requirements and design bases in design work and design changes. (3) Identify and control design interfaces. (4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work. (5) Verify or validate work before approval and implementation of the design.	Generally equivalent. 10 CFR 71 Subpart H includes additional requirements for design control/verification.

10 CFR 71 Subpart H Requirement	10 CFR 830 Subpart A/ DOE O 414.1C Criteria	Comments/Gap Analysis
maintenance, and repair; (4) Features to facilitate decontamination; and (5) Delineation of acceptance criteria for inspections and tests. (c) The licensee, certificate holder, and applicant for a CoC shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the CoC require prior NRC approval.		
71.109 – Procurement Document Control The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that adequate quality is required in the documents for procurement of material, equipment, and services, whether purchased by the licensee, certificate holder, and applicant for a CoC or by its contractors or subcontractors. To the extent necessary, the licensee, certificate holder, and applicant for a CoC shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this part.	831.121 (4) Describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the criteria of § 830.122.	Generally equivalent.
71.111 – Instructions, Procedures, and Drawings The licensee, certificate holder, and applicant for a CoC shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.	5 – Performance/Work Processes (1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means. 4 – Management/ Documents and Records (1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.	Generally equivalent. In addition, 10 CFR 71 Subpart H requires that acceptance criteria be included in instructions, procedures, and drawings.
71.113 – Document Control The licensee, certificate holder, and applicant for a CoC shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, that prescribe all activities affecting	4 – Management/ Documents and Records (1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements,	In general, Criterion 4 is applicable to all sections of 10 CFR 71 Subpart H that require written documents.

10 CFR 71 Subpart H Requirement	10 CFR 830 Subpart A/ DOE O 414.1C Criteria	Comments/Gap Analysis
quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed.	or establish design.	
71.115 – Control of Purchased Material, Equipment, and Services (a) The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products on delivery. (b) The licensee, certificate holder, and applicant for a CoC shall have available documentary evidence that material and equipment conform to the procurement specifications before installation or use of the material and equipment. The licensee, certificate holder, and applicant for a CoC shall retain, or have available, this documentary evidence for the life of the package to which it applies. The licensee, certificate holder, and applicant for a CoC shall assure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment. (c) The licensee, certificate holder, and applicant for a CoC shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.	7 – Performance/ Procurement (1) Procure items and services that meet established requirements and perform as specified. (2) Evaluate and select prospective suppliers on the basis of specified criteria. (3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.	Generally equivalent. Additional specificity in 10 CFR 71 Subpart H for procurement records.
71.117 – Identification and Control of Materials, Parts, and Components The licensee, certificate holder, and applicant for a CoC shall establish measures for the identification and control of materials, parts, and components. These measures must assure that identification of the item is maintained by heat number, part number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, installation, and use of the item. These	5 – Performance/Work Processes (2) Identify and control items to ensure their proper use.	Supplementation is needed to comply with the traceability requirements of this section of 10 CFR 71 Subpart H.

10 CFR 71 Subpart H Requirement	10 CFR 830 Subpart A/ DOE O 414.1C Criteria	Comments/Gap Analysis
identification and control measures must be designed to prevent the use of incorrect or defective materials, parts, and components.		
71.119 – Control of Special Processes The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that special processes, including welding, heat treating, and nondestructive testing are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.	2 – Management/Personnel Training and Qualification (1) Train and qualify personnel to be capable of performing their assigned work. (2) Provide continuing training to personnel to maintain their job proficiency.	No specific requirement, however Criterion 2 is generally applicable. Supplementation is needed in order to comply with 10 CFR 71 Subpart H.
71.121 – Internal Inspection The licensee, certificate holder, and applicant for a CoC shall establish and execute a program for inspection of activities affecting quality by or for the organization performing the activity, to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The inspection must be performed by individuals other than those who performed the activity being inspected. Examination, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If direct inspection of processed material or products is not carried out, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when quality control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the licensee's designated representative and beyond which work should not proceed without the consent of its designated representative, are required, the specific hold points must be indicated in appropriate documents.	8 – Performance/ Inspection and Acceptance Testing (1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.	No specific requirement for independence of inspectors, although 10 CFR 830 Subpart A/ DOE O 414.1C generally requires independence (e.g., for independent assessments, design verification). Supplementation may be needed. Additional specificity in 10 CFR 71 Subpart H for process monitoring vs. direct inspection, and hold points.
71.123 – Test Control The licensee, certificate holder, and applicant for a CoC shall establish a test program to assure that all testing required to demonstrate that the packaging components will perform satisfactorily in service is identified and performed in accordance with written test procedures that incorporate the requirements of this part and the requirements and acceptance limits contained in the package approval. The test procedures must include provisions for assuring that all prerequisites for the given test are met, that	8 – Performance/ Inspection and Acceptance Testing (1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.	Generally equivalent, but 10 CFR 71 Subpart H has additional specificity for the content of test procedures, instrumentation, and environmental conditions.

10 CFR 71 Subpart H Requirement	10 CFR 830 Subpart A/ DOE O 414.1C Criteria	Comments/Gap Analysis
adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. The licensee, certificate holder, and applicant for a CoC shall document and evaluate the test results to assure that test requirements have been satisfied.		
71.125 – Control of Measuring and Test Equipment The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy within necessary limits.	5 – Performance/Work Processes (4) Calibrate and maintain equipment used for process monitoring or data collection. 8 – Performance/ Inspection and Acceptance Testing (2) Calibrate and maintain equipment used for inspections and tests.	Generally equivalent.
71.127 – Handling, Storage, and Shipping Control The licensee, certificate holder, and applicant for a CoC shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.	5 – Performance/Work Processes (3) Maintain items to prevent their damage, loss, or deterioration.	Generally equivalent. Additional specificity is provided in 10 CFR 71 Subpart H for protective environments.
71.129 – Inspection, Test, and Operating Status (a) The licensee, certificate holder, and applicant for a CoC shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests. (b) The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.	5 – Performance/Work Processes (2) Identify and control items to ensure their proper use.	Generally equivalent except that supplementation is needed to meet the additional specificity of 10 CFR 71 Subpart H with regards to identification/labeling of items as to their inspection and test status, and prevent the inadvertent operation of packaging components.
71.131 – Nonconforming Materials, Parts, or Components The licensee, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent	3 – Management/Quality Improvement (1) Establish and implement processes to detect and prevent quality problems.	Generally equivalent. 10 CFR 71 Subpart H provides additional specificity regarding the control of nonconforming items

10 CFR 71 Subpart H Requirement	10 CFR 830 Subpart A/ DOE O 414.1C Criteria	Comments/Gap Analysis
their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.	(2) Identify, control, and correct items, services, and processes that do not meet established requirements.	and materials.
71.133 – Corrective Action The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.	3 – Management/Quality Improvement (1) Establish and implement processes to detect and prevent quality problems. (3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem. (4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.	Generally equivalent.
71.135 – Quality Assurance Records The licensee, certificate holder, and applicant for a CoC shall maintain sufficient written records to describe the activities affecting quality. The records must include the instructions, procedures, and drawings required by § 71.111 to prescribe quality assurance activities and must include closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures which establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee, certificate holder, and applicant for a CoC shall retain these records for 3 years beyond the date when the licensee, certificate holder, and applicant for a CoC last engage in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee, certificate holder, and applicant for a CoC shall retain the superseded material for 3 years after it is superseded.	4 – Management/ Documents and Records (2) Specify, prepare, review, approve, and maintain records.	Supplementation is needed to comply with the detailed requirements of this section of 10 CFR 71 Subpart H.
71.137 – Audits	9 – Assessment/ Management	Management assessments are not

10 CFR 71 Subpart H Requirement	10 CFR 830 Subpart A/ DOE O 414.1C Criteria	Comments/Gap Analysis
The licensee, certificate holder, and applicant for a CoC shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, must be taken where indicated.	Assessment Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives. 10 – Assessment/ Independent Assessment (1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. (2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments. (3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.	directly required by 10 CFR 71 Subpart H. Specific requirements of 10 CFR 71 Subpart H related to audits need to be included in the QA program.

7. References

a. Code of Federal Regulations, Office of the Federal Register, Washington, D.C.

(1) Title 10, Part 71, *Packaging and Transportation of Radioactive Materials.*

(2) Title 10, Part 71 Subpart H, *Quality Assurance*, January 1, 2007

(2) Title 10, Part 830, *Nuclear Safety management*.

(3) Title 10, Part 830 Subpart A, *Quality Assurance Requirements*, January 1, 2007

(4) Title 10 Part 50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, January 1, 2007

(5) Title 29, Part 1910, *Occupational Safety and Health Standards*.

(6) Title 40, Parts 260-281, *Environmental Protection Agency Regulations*.

(7) Title 49, Parts 105-199, *Hazardous Materials Regulations*.

(8) Title 49, Parts 350-399, *Federal Motor Carrier Safety Regulations*.

b. American National Standards Institute, American National Standards Institute, New York.

(1) N14.1-2001, *Packaging of Uranium Hexafluoride for Transport*, addendum 1, 2002.

(2) N14.5-1997, *Leakage Tests on Packages for Shipment*, 1997.

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ATTACHMENT 1

Selected Chronological Milestones Concerning Department of Energy Orders 1540.2, 5480.3 and 460.1

1985. The Department of Energy (DOE) Order 5480.3 provided for a packaging certification program where each field office was allowed to perform its own certifications.

Following a congressional inquiry, the program was changed, and a centralized certification program was established at DOE Headquarters in 1985 under Defense Programs (DP). This centralized program was proscribed in DOE 1540.2. Management of transportation operations was also under DP at this time.

However, DOE 5480.3, which addresses packaging and transportation safety, was not changed. Therefore, one Order allows certification at the field office level, and one does not. (A memorandum was issued that clearly removed the authority from the field, but DOE 5480.3 was never changed.)

1987. Defense Programs requested that the Office of Environment, Safety and Health (EH) update DOE 5480.3 to reflect the current organizational responsibilities as well as correct 21 areas where the Order conflicted with the Department of Transportation/Nuclear Regulatory Commission packaging and transportation regulations used by DOE (essentially Title 10, *Code of Federal Regulations*, Part 71, and Title 49, *Code of Federal Regulations*, Part 173).

EH was also requested to issue a Notice to the Order clarifying the issues until the Order could be revised. Although Notices were issued, the Notices have expired without any revisions to the Order: therefore, the current Order continues to reflect the conflicts.

1989–1992 Reorganizations. The Office of Environmental Restoration and Waste Management (EM) were formed, and the management of transportation operations function was transferred from DP to EM. Also, during this period, the certification function was transferred from DP to EH.

These changes left the Orders in a status where they were not only in conflict with one another and with the federal regulations, but no longer reflected any correct organizational structure or responsibilities. For example, both Orders showed DP with the major programmatic responsibilities for packaging and transportation operations and safety.

1992. EH and EM began a concerted effort to update the Orders. Since previous reorganizations had transferred major responsibilities from DP and split them between EH and EM, the Order revision effort involved revamping the existing five transportation and packaging Orders 1540.1,

1540.1A, 1540.3, 1540.4, and 5480.3 into eight Orders 1540.1A, 1540.2A, 1540.3A, 1540.4A, 1540.5A, 1540.6A, 5480.3R, and 5480.X (onsite safety).

> The intent was to cancel DOE 1540.2 and transfer its safety requirements to DOE 5480.3R, the successor to DOE 5480.3 which was being totally rewritten. DOE 1540.2 was to be reissued as a new Order with a different title and different requirements.

1994. Draft Orders 5480.3R, 5480.X, and 5480.3V (Motor Carrier Safety) were completed.

1995. As part of the Directives Reduction Initiative, DOE O 460.1 was issued which contained the surviving portions of the three 1994 Safety Orders. At the same time the revisions to the 1540 series took place in the form of DOE O 460.2.

1996. DOE O 460.1A replaced DOE O 460.1 when the EH packaging and transportation safety functions were transferred to EM.

1997. DOE G 460.1-1 is issued.

2003. DOE O 460.1B replaced DOE O 460.1A.

2007. DOE O 460.1C to replace DOE O 460.1B

2007. DOE G 460.1-1A to replace DOE G 460.1-1

ATTACHMENT 2

Letter, Judith S. Kaleta, Chief Counsel, U. S. Department of Transportation to Susan H. Denny, Director, Transportation Management Division, U. S. Department of Energy, April 23, 1991

U.S. Department of Transportation
Research and Special Programs Administration

Office of the Chief Counsel

400 Seventh St., S.W.
Washington, D.C. 20590

APR 23 1991

Ms. Susan H. Denny
Director
Transportation Management Program
Office of Technology Development
Department of Energy
Washington, DC 20585

Dear Ms. Denny:

I am responding to your March 25 request for a definition of "public highway" in the context of the Hazardous Materials Transportation Act (HMTA), 49 App. U.S.C. 1801 et seq., and the Hazardous Materials Regulations (HMR), 49 C.F.R. Parts 171-180, issued under the HMTA. Because the applicability of the HMTA depends upon the existence of "transportation in commerce" (49 App. U.S.C. 1801, 1803, 1804), I will discuss the issues in terms of whether there is transportation in commerce rather than whether there is transportation on public highways.

On November 16, 1990, the HMTA was amended by the Hazardous Materials Transportation Uniform Safety Act of 1990 (HMTUSA), Public Law 101-615. Section 3 of the HMTUSA added a definition of "person" to 49 App. U.S.C. 1802 that makes it clear that government agencies offering hazardous materials for transportation in commerce or transporting hazardous materials in furtherance of a commercial enterprise are subject to the HMTA. It states:

> The term 'person' means . . . government, Indian tribe, or agency or instrumentality of any government or Indian tribe when it offers hazardous materials in furtherance of a commercial enterprise, but such term does not include (a) the United States Postal Service, or (B) for the purposes of sections 110 and 111 [penalties and specific relief, respectively] of this title, any agency or instrumentality of the Federal Government.

Also, Section 20 of the HMTUSA added 49 U.S.C. App. 1818 to provide that the HMTA applies to contractors with, among others, the Federal Government. It states:

> Any person who, under contract with any department, agency, or instrumentality of the executive, legislative, or judicial branch of the Federal government, transports, or causes to be transported or shipped, a hazardous material . . . shall be subject to and comply with all provisions of this title, all orders and regulations issued under this title, and all other substantive and procedural requirements of Federal, State and local governments and Indian tribes (except any such requirements that have been preempted by this title or any other Federal law), in the same manner and to the same extent as any person engaged in such activities that are in or affect commerce is subject to such provisions, orders, regulations, and requirements.

Therefore, the Department of Energy (DOE) is required to comply with the HMR when it offers hazardous materials for transportation or transports them in commerce. DOE, however, is not required to comply with the HMR when it offers or transports hazardous materials in a Government vehicle because those DOE activities are presumed to be for a governmental purpose and thus not in commerce.

DOE's contractors, however, must comply with the HMR even when the transportation is in a Government vehicle -- unless the transportation is not in commerce (a prerequisite to the applicability of the HMTA and the HMR).

Transportation on (across or along) roads outside of Government properties generally is transportation in commerce. Transportation on Government properties requires close analysis to determine whether it is in commerce. If a road is used by members of the general public (including dependents of Government employees) without their having to gain access through a controlled access point, transportation on (across or along) that road is in commerce. On the other hand, if access to a road is controlled at all times through the use of gates and guards, transportation on that road is not in commerce.

One other means of preventing hazardous materials transportation on Government property from being in commerce is to temporarily block access to the section of the road being crossed or used for that transportation. The road would have to be blocked by persons having the legal authority to do so, and public access to the involved section of road would have to be effectively precluded.

The following discussion applies these general principles to the situations described in your letter.

Example 1: Road A is located on DOE-owned property and is maintained by DOE. Speed enforcement is by a DOE contractor. The road has unrestricted public access, but there are signs stating that persons are entering DOE property. Analysis: Road A has unrestricted public access, and, therefore, transportation on or across it is subject to the HMR.

Example 2: Road B traverses a DOE site, but is maintained by the State. Speed enforcement is by the State. The DOE cannot unilaterally block the road. There is unrestricted public access, except for times when DOE/State Police physically block public access in order to make special shipments. Analysis: Because there is unrestricted public access to Road B, transportation on or across it is subject to the HMR. However, effective blocking of public access (as described above) by DOE or State officials would avoid application of the HMR.

Example 3: Road C connects two DOE sites, is owned by the city and is maintained by DOE under a legal agreement. Speed enforcement is by the city. The public has unrestricted access. Analysis: Road C is not on Government property; thus, the HMR would apply.

Example 4: Road D is on DOE-owned property and is maintained by DOE. Speed enforcement is by a DOE contractor. The road is posted with a sign restricting usage to those on official government business, but there are no physical barriers. Analysis: Because there is public access to Road D, the HMR would apply there. This result could be changed either by effectively blocking public access or by controlling public use at all times through the use of gates and guards.

As indicated above, transporting a hazardous material across a road or doing so along a road both are subject to the HMR unless the section of the road involved is removed from commerce by one of the above-described actions.

I trust that this information will be useful to you in providing guidance to your operating contractors. Please advise me if additional information or clarification is desired.

Sincerely,

Judith S. Kaleta
Chief Counsel

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ATTACHMENT 3

Letter, E. H. Bonekemper, Assistant Chief Counsel, U. S. Department of Transportation to Jo Ann Williams, Office of Chief Counsel, U. S. Department of Energy, April 26, 1993

93-263

US Department of Transportation
Research and Special Programs Administration

Office of the Chief Counsel

400 Seventh St., S.W.
Washington, D.C. 20590

APR 26 1993
Read at CRM-4
5/3/93

Ms. Jo Ann Williams
Office of Chief Counsel (GC-12)
U.S. Department of Energy
Washington, D.C. 20585

Dear Ms. Williams:

On April 15, 1993, at a meeting attended by representatives of this office, the Federal Highway Administration, the Department of Energy (DOE) and the University of California, we discussed the application of the Hazardous Materials Transportation Act (HMTA), 49 App. U.S.C. §§ 1801 et seq., to hazardous materials transportation at the Los Alamos National Laboratory (LANL). This meeting followed an inquiry to the Research and Special Programs Administration (RSPA) from the University's LANL Counsel, Ellen M. Castille. Specifically, Ms. Castille inquired whether the HMTA and its implementing regulations, 49 C.F.R. Parts 171-180 (the Hazardous Materials Regulations or HMR), apply to the transportation of hazardous materials by the University in its capacity as operator, under contract to the DOE, of the LANL.

This letter sets out the jurisdictional framework of the HMTA as it applies to hazardous materials transportation by Federal agencies and their contractors. Although RSPA exercises rulemaking authority under the HMTA with respect to all hazardous materials transportation in commerce, enforcement authority over land-based transportation is shared with the Federal Highway Administration and the Federal Railroad Administration.

The HMTA, as amended by the Hazardous Materials Transportation Uniform Safety Act, Pub. L. No. 101-615, 104 Stat. 3244 (1990), applies to "any person" who transports hazardous materials in commerce. 49 App. U.S.C. § 1804(a)(3). The term "person" includes any:

> government or Indian tribe when it offers hazardous materials for transportation in commerce or transports hazardous materials in furtherance of a commercial enterprise....

Id. at § 1830(11). Hazardous materials transportation by a Federal, State or local government agency or an Indian tribe, then, is subject to regulation under the HMTA when that transportation is "in furtherance of a commercial enterprise." RSPA defines this term by its converse: governmental transportation is not in furtherance of a commercial enterprise when it is carried out (1) by government personnel and (2) for a governmental purpose.

The sphere of "governmental purpose" cannot be delineated in the abstract. When the activity in conjunction with which the transportation occurs is constitutionally mandated or authorized, when it is a traditional "sovereign" activity or one falling within the police power, or when its benefits accrue to the public as a whole, it is likely to fall within the realm of the governmental purpose. The purpose is more apt to be deemed non-governmental if there is a conscious purpose to generate a profit, if the activity is undertaken by a public corporation with limited liability, or if the activity competes with, or displaces, the private sector. Each case must be considered on its facts.

When the transporter is not the Federal Government itself, but a Federal contractor, the HMTA provides:

> Any person who, under contract with any department . . . of the Federal government, transports, or causes to be transported or shipped, a hazardous material . . . shall be subject to and comply with all provisions of [the HMTA], all orders and regulations issued under [the HMTA], and all other substantive and procedural requirements of Federal, State and local governments and Indian tribes (except such requirements that have been preempted by this chapter or any other Federal law), in the same manner and to the same extent as any person engaged in such activities that are in or affect commerce is subject to such provisions, orders, regulations, and requirements.

49 App. U.S.C. § 1818. This provision, added to the statute by the 1990 amendment, merely clarified existing law. See H. Rep. No. 101-444 (Part 2), 101 Cong., 2d Sess. 43 (1990) ("It is the Committee's firm position that [section 1818] simply restates existing law."). The provision means that a Federal contractor cannot claim sovereign immunity and does not share in the

exception from HMTA jurisdiction conferred on the governmental agency itself. Therefore, the contractor's transportation activity is subject to HMTA regulation if that activity is "in commerce."

RSPA accords the "in commerce" requirement its accepted meaning. See 49 App. U.S.C. § 1802(2) (defining transportation in "commerce" as transportation that is or affects interstate trade or traffic). Thus, the HMTA does not apply to transportation that is entirely on private property and neither follows nor crosses a public way. Analogously, transportation by a Federal contractor is not in commerce if it takes place entirely on Federal property to which there is no general public right of access, or if public access legally is denied during the period of transportation.

Were the University of California not itself a government agency, its transportation of hazardous materials in the performance of its contractual duties would be subject to the HMTA, to the extent transportation occurred on public roads. However, because the University is a governmental body, its hazardous materials transportation as the operator of the Los Alamos National Laboratory, on public roads or not, is not subject to the HMTA, provided that transportation is by government personnel and for a governmental purpose.

The HMR, however, may impose requirements on the University of California irrespective of its status as a governmental body or Federal contractor, and whether or not the transportation in which it engages is in commerce. For example, the requirement that every bulk oil transporter prepare and maintain a spill response plan would apply to the University, even as a State agency and a Federal contractor, and even were its transportation not in commerce. 49 C.F.R. at § 171.5 (interim final rule promulgated at 58 Fed. Reg. 6864, February 2, 1993).

Conversely, governmental bodies are exempt from the registration and fee requirements of 49 C.F.R. Subpart 107.600, even where they transport hazardous materials in commerce. 49 C.F.R. § 107.606. And where transportation otherwise would be subject to the HMTA, it may be excepted from regulation by a specific code provision (e.g., 49 C.F.R. §§ 173.7(b) and 177.806(b), excepting certain national security shipments of Class 7 radioactive materials).

Where the University's hazardous materials transportation, or some part of it, is exempted from HMTA jurisdiction, the University and DOE still may find it desirable to agree, or DOE may choose to require, that transaportation shall be in accordance with HMR standards. Such a course may be sensible,

particularly given that it may not always be clear where the line between governmental and non-governmental purpose lies. This decision, however, would be one not of the application of the HMTA, but rather of contractual obligations owed to the DOE by the University apart from HMTA or U.S. Department of Transportation jurisdiction. If the HMR did not otherwise apply, the University's agreement, voluntary or through contract, to comply with the HMR would not invoke U.S. DOT enforcement jurisdiction.

I trust this guidance is of assistance to you. Please feel free to call me at 202-366-4400 if you have any further questions on this matter.

Sincerely,

Edward H. Bonekemper, III
Assistant Chief Counsel
Hazardous Materials Safety &
Research and Technology
Law

cc: Ellen M. Castille
Larry G. Blalock
Paul Brennan

ATTACHMENT 4

Capability of Test Facilities for Testing Type A Packagings

The following sections present details on the test facility requirements for the Type A packaging tests and the pass/fail criteria for each test.

Chemical Compatibility Test for Plastic Packagings and Receptacles

A chemical compatibility test for plastic packagings and receptacles designed to transport liquid contents is required by 49 CFR 173.24(e)(3)(ii). The test facility should be capable of filling three of the plastic packagings or receptacles to rated capacity with the specific hazardous material to be transported, storing them at one of the specified test temperatures for the test duration required by Appendix B to 49 CFR 173, inverting the containers for the required times at the beginning and end of the storage period, and determining the weight loss of hazardous materials contents during the storage period. After storage, a test facility should be capable of draining, rinsing, and refilling the containers with water to their rated capacity, then dropping the containers at ambient temperature from the height required by Appendix B onto a rigid non-resilient, flat and horizontal surface. A test facility should also be capable of evaluating the containers for visible evidence of permanent deformation due to:

- vapor pressure buildup,
- collapse of walls,
- deterioration,
- swelling,
- crazing,
- cracking,
- excessive corrosion,
- oxidization,
- embrittlement,
- leakage,
- rupture,
- or for evidence of other defects likely to cause premature failure or a hazardous condition.

In addition, a test facility should be capable of calculating the rate of permeation over the test period and comparing it to the permeation limits of Appendix B. Alternative procedures or rates of permeation are permitted by 49 CFR 173.24(e)(3)(iii) if they yield a level of safety equivalent to or greater than that provided by 173.24(e)(3)(ii) and are specifically approved by the Associate Administrator for Hazardous Materials Safety at DOT. Justification and procedures would have to be developed by the test facility and submitted to EM. If EM approved the request and the supporting documentation, EM would then submit the application to DOT.

Each test facility should have procedures describing the equipment to be used for the required storage, permeation evaluation, and drop test. The test procedure should describe the test equipment, discuss how the storage temperature would be maintained, state how the various storage configurations would be achieved and timed, describe how the rate of permeation would be determined, document the maximum package size (external dimensions and weight) the apparatus is capable of testing, describe the means of assuring proper drop height, provide pass/fail criteria for the test, and list the records to be kept of both testing and results.

Evidence of any of the following conditions constitutes test failure:

- a rate of permeation in excess of the permeation limits of Appendix B or
- any visible evidence of permanent deformation of any of the containers or
- other defects likely to cause premature failure or otherwise result in a hazardous condition.

Vibration Test

A vibration test for non-bulk packaging is required by 49 CFR 173.24a(a)(5). Non-bulk packaging is defined in 49 CFR 171.8 as a packaging with (1) an internal volume of 450 liters (119 gallons) or less as a receptacle for a liquid; (2) a capacity of 400 kg (882 lb) or less and an internal volume of 450 l (119 gal) or less as a receptacle for a solid; or (3) a water capacity of 454 kg (1,000 lb) or less as a receptacle for a gas. Any Type A packagings not fitting this description must also be vibration tested as directed in 49 CFR 173.410(f).

The vibration test facility must be capable of placing three sample packagings, filled and closed as for shipment, on a vibrating platform with a vertical or rotary double-amplitude (peak-to-peak displacement) of 1 inch. The packages should be constrained horizontally to prevent them from falling off the platform, but should be left free to move vertically, bounce and rotate. The test must be performed for 1 hour at a frequency causing the package to be raised from the vibrating platform

sufficiently to permit a piece of material of approximately 1.6 mm (0.063 inch) thickness (such as steel strapping or paperboard) to pass between the bottom of any package and the platform. Immediately following the period of vibration, each package must be removed from the platform, turned on its side and inspected for any evidence of leakage. Other test methods must be at least equally effective and approved by the Associate Administrator for Hazardous Materials Safety.

A test facility should provide documentation describing its vibration test apparatus and demonstrating it meets the test requirements specified in 49 CFR 178.608. The vibration test procedure should describe the vibration test equipment, document the maximum package size (external dimensions and weight) the apparatus is capable of testing, describe the means of assuring the proper vibration amplitude, provide pass/fail criteria for the test, and list the records to be kept of both testing and results. Any package design showing evidence of rupture or leakage fails this test.

Reduced Ambient Pressure Test

A reduced ambient pressure test should be conducted to verify the Type A package design requirement found in 49 CFR 173.412(f). To perform this test, a test facility should be capable of subjecting the containment system to a reduced ambient pressure of 25 kPa (3.5psi) or otherwise creating an equivalent pressure differential. A test facility should have procedures describing the equipment to be used for the test, the range of packaging sizes capable of being tested, test operations, the test duration, the pass/fail criteria for the test, and records to be kept of the testing and results. Any package design showing evidence the containment system would not retain its radioactive contents fails this test.

Water Spray Test

A water spray test is required for Type A packages by 49 CFR 173.465(b). To perform this test, a test facility should be capable of simulating exposure to rainfall of approximately 5 cm (2 in.) per hour for at least 1 hour. Water spray should either be applied from four different directions simultaneously, in which case an interval of 2 hours should elapse before the next test is performed on the packaging, or from each of four directions consecutively in which case no time should elapse before the next test is performed.

Each test facility should have procedures describing the equipment to be used for the water spray test. The procedures must define any calibration requirements needed to ensure a water spray of 5 cm (2 in.) per hour, how the test will be conducted and timed, pass/fail criteria for the test, and the records to be kept of both testing and results. Any evidence of the following constitutes failure of

this test: (1) loss or dispersal of the radioactive contents, or (2) any significant increase in the radiation levels recorded or calculated at the external surfaces of the packaging. Because any radiation level increase would be dependent on the radioactive package contents, this criterion should be evaluated for specific package contents whenever damage to the packaging occurs as a result of the test. The test facility should document any decrease in the effectiveness of package shielding in a way enabling determination of acceptability to be made by any package user for any contents.

Free Drop Test

A free drop test is required for Type A packages by 49 CFR 173.465(c). For liquids and gases, an additional test is specified in 49 CFR 173.466(a)(1). To perform these tests, a test facility should be capable of dropping a packaging onto a flat and horizontal surface with the mass and rigidity specified in 49 CFR 173.465(c)(5). The test apparatus should be capable of handling both small and large packagings, and should be capable of performing drops ranging from 0.3 m (1 ft) to 9 m (30 ft).

Each test facility should provide documentation describing its drop test apparatus and demonstrate how its target surface meets the mass and rigidity requirements of 49 CFR 173.465(c)(5). The drop test procedure should document the maximum package size (external dimensions and weight) the apparatus is capable of testing, the method(s) for lifting and dropping packagings of various sizes and types, the method to determine the maximum-damage drop orientation for each packaging, the method to ensure the appropriate drop orientation and drop height during testing, pass/fail criteria for the drop tests, and the records to be kept (including photographs and/or videotape) of both testing and results. Any evidence of the following would constitute failure of this test: (1) loss or dispersal of the radioactive contents, or (2) any significant increase in the radiation levels recorded or calculated at the external surfaces of the packaging. Because any radiation level increase would be dependent on the radioactive package contents, this criterion should be evaluated for specific package contents whenever the test imparts damage to the packaging. The test facility should document any decrease in the effectiveness of package shielding in a way that will enable determination of acceptability to be made by any package user for any contents.

Stacking

A compression test is required for Type A packages by 49 CFR 173.465(d). To perform this test, a test facility should be capable of applying a compressive load uniformly to two opposite sides of a packaging specimen, one of which should be the base on which the package would normally stand, for a period of at least 24 hours. The compressive load shall be at least of either five times the mass of the actual package or the equivalent of 13 kPa (1.9 psi) multiplied by the projected area (footprint) of the package.

Each test facility should have procedures describing the apparatus used for compression tests, how the compression test is performed for various packaging sizes and shapes, how the compressive load is determined for each packaging, pass/fail criteria for the test, and the records to be kept of both testing and results. Any evidence of the following would constitute failure of this test: (1) loss or dispersal of the radioactive contents, or (2) any significant increase in the radiation levels recorded or calculated at the external surfaces of the packaging. Because any radiation level increase would be dependent on the radioactive package contents, this criterion should be evaluated for specific package contents whenever damage to the packaging occurs as a result of the test. The test facility should document any decrease in the effectiveness of package shielding in a way that will enable determination of acceptability to be made by any package user for any contents.

Penetration Test

A penetration test is required for Type A packages by 49 CFR 173.465(e). An additional test for Type A packagings designed for liquids and gases is specified in 49 CFR 173.466(a)(2). To perform these tests, a test facility should be capable of evaluating a packaging to determine where it is most vulnerable to puncture, then placing a packaging specimen on a rigid, flat, horizontal surface that will not move significantly during testing and dropping a 3.2 cm (1.25 in.) diameter, 6 kg (13.2 lb) bar with a hemispherical end onto the most vulnerable part of the packaging, from a distance of 1 m (3.3 ft) or greater with its longitudinal axis vertical.

Each test facility should have documented procedures describing the method to determine most vulnerable to penetration of the packaging, test operations, pass/fail criteria for the test, and the records to be kept (including photographs and/or videotape) of both testing and results. Any evidence of the following would constitute failure of this test: (1) loss or dispersal of the radioactive contents, or (2) any significant increase in the radiation levels recorded or calculated at the external surfaces of the packaging. Because any radiation level increase would be dependent on the

radioactive package contents, this criterion should be evaluated for specific package contents whenever damage to the packaging occurs as a result of the test. The test facility should document any decrease in the effectiveness of package shielding in a way that will enable determination of acceptability to be made by any package user for any contents.

ATTACHMENT 5

Quality Assurance for Contractor Testing Facilities

The following criteria for management, performance, and assessment pertain to establishing quality assurance for contractor testing facilities.

Management -- DOE O 414.1C specifies four management quality assurance criteria.

> Criterion 1—Program. Organizations shall develop, implement, and maintain a written Quality Assurance Program (QAP). The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work. The QAP shall describe the management processes, including planning, scheduling, and providing resources of work.

Each test facility should operate under a documented QAP. This documentation should be provided to EM for review as part of the approval process for the test facility.

> Criterion 2—Personnel Training and Qualification. Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel training shall be refreshed periodically to maintain proficiency.

The various review and testing tasks which should be performed as part of this program should be defined. Minimum personnel qualifications should then be established for each of these tasks. Personnel reviewing the applicant's documentation and evaluating test results should be technically qualified to do so, particularly in mechanical design areas such as lifting and tie down requirements. Personnel determining worst-case drop orientations should also be qualified to do so. Personnel performing the tests should be trained in the test requirements and test procedures. Documentation of the defined tasks and qualification requirements for each should be provided to EM for review as part of the approval process for each test facility.

A procedure for qualifying personnel to perform the defined tasks should also be provided to EM. The procedure should include establishment and maintenance of training records, where appropriate.

> Criterion 3—Quality Improvement. The organization shall establish and implement processes to detect and prevent quality problems and to ensure quality improvement. Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected. Correction shall include identifying the causes of problems and preventing recurrence. Item characteristics, process implementation, and other quality-related information shall be reviewed to identify items, services, and processes needing improvement.

Each test facility should provide documentation demonstrating that the test facility organization has established quality improvement processes and that the test facility operates under these established

processes. This documentation should be provided to EM for review as part of the approval process for the test facility.

> Criterion 4—Documents and Records. Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained.

As discussed in Section 4, each test facility is required to have a set of procedures fully documenting the how it processes an application for a Type A package evaluation. The procedures should cover both the review of the applicant's documentation and the testing which is performed on the packaging subsequent to the documentation review. These procedures should be provided to EM for review as part of the approval process for the test facility.

The procedures should be prepared, reviewed, approved, issued, used, and revised under a formal document control system. Documentation of the formal document control system should also be provided to EM for review as part of the approval process for the test facility.

Each procedure should document the records to be maintained as a result of implementation of that procedure. Records should provide adequate detail to ensure correct implementation of the procedure and the proper conclusions regarding the packaging. For some tests (e.g., the drop tests) visual records (photographs and/or videotape) may be appropriate. Appropriate records include:

a. applicant's design packet;
b. documentation of review of applicant's design packet, including comment resolution where appropriate;
c. records of the testing and results, including photographs and/or videotape where appropriate;
d. documentation developed by test facility of testing and results and
e. records of review and approval of the documentation by EM.

Records to be maintained should also include documentation of the test facility program and procedures, including:

a. documentation of procedures and procedure revisions;
b. documentation of equipment qualification and maintenance, where appropriate;
c. documentation of review and approval of test facility procedures and equipment by EM;
d. task descriptions; and
e. personnel qualifications for individuals performing defined tasks.

Records should be maintained under a formal records maintenance system covering retention, protection,

preservation, traceability, accountability, and retrievability of records. Documentation of the records maintenance system for the test facility organization should be provided to EM for review as part of the approval process for the test facility.

Performance -- DOE O 414.1C specifies four performance quality assurance criteria.

> Criterion 5—Work Processes. Work shall be performed to established technical standards and administrative controls. Work shall be performed under controlled conditions using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.
>
> Criterion 6—Design. Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design.

This program performs design verification activities rather than design work. As such, most of the elements of this criterion do not apply. Careful documentation of the design being reviewed, including documentation of any design changes resulting from the review, should be assured so that verification of the correct design is established. This program already ensures that verification and validation of the package design are completed before the packaging is approved for use. Independence of personnel performing design verification from package design should also be ensured. Documentation should be provided to EM demonstrating that (1) the test facility will ensure that verification of the correct design is established and (2) personnel performing the design verification activities are independent of package design efforts. This documentation should be provided to EM for review as part of the approval process for the test facility.

> Criterion 7—Procurement. The organization shall ensure that procured items and services meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. The organization shall ensure that approved suppliers can continue to provide acceptable items and services.

This criterion should be applied to the procurement of test apparatus and any other items procured in support of this program. Each test facility organization should have a documented procurement program to accomplish this. Documentation of the procurement program for the test facility organization should be provided to EM for review as part of the approval process for the test facility.

> Criterion 8—Inspection and Acceptance Testing. Inspection and acceptance testing of specified items, services, and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained.

Inspection and acceptance testing of test apparatus should be specifically addressed in the test procedures, where appropriate.

Assessment -- DOE O 414.1C specifies two assessment quality assurance criteria.

> Criterion 9—Management Assessment. Management at all levels shall periodically assess the integrated quality assurance program and its performance. Problems that hinder the organization from achieving its objectives shall be identified and corrected.

Each test facility should provide documentation demonstrating that the test facility organization has an established management assessment program, and that the test facility operates within this management

> Criterion 10—Independent Assessment. Independent assessments shall be planned and conducted to measure item service, quality, adequacy of work performance and to promote improvement. The organization performing independent assessments shall have sufficient authority and freedom from the line management to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas to be assessed.

Each test facility should provide documentation demonstrating that the test facility organization has an established independent assessment program, and that the test facility operates within this independent assessment program. This documentation should be provided to EM for review as part of the approval process for the test facility.